BLENDED SMOKING CESSATION TREATMENT

USER EXPERIENCE | ADHERENCE | EFFECTIVENESS

Lutz Siemer

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PREFACE

Dear reader,

How pleasant that this work has aroused your interest. It is 2020 and the finalizing of this PhD project takes place in a phase in which public and private life is dominated by the COVID-19 pandemic 2019-2020. Social distancing, home office and home schooling determine everyday life and people use digital means to stay in touch professionally and privately.

Due to the biological threat of a disease-causing virus, web-based communication suddenly appears safe and is preferred to face-to-face communication. A stubborn tiny chunk of protein has finally released the digital handbrake.

The topic of this work - the blending of face-to-face and web-based interaction - thus gains further relevance. Even though the related question of whether this blending offers “the best of both worlds” is apparently decided by practical necessity in people’s digital corona everyday life. All the more reason for a thorough examination of the blending of face-to-face and web-based interactions.

Blending is an art in itself and so with whiskey and wine and of course with the ultimate question of whether vodka martini should be shaken or stirred[1], there is a lot of wrangling about the optimal blend.

The same can be found in education and medicine, where blended learning and blended treatment is becoming increasingly common. Here, too, the optimal blend is sought. Let us immerse ourselves a little in the discussion of blended treatment with this thesis.

Lutz Siemer
Germany/The Netherlands, September 2020

1 According to a certain J. Bond, of course, the only correct answer is “Shaken, not stirred”.

CONTENT

1

General introduction

Alexandra is 56 years old. She lives alone and due to an illness, she is very reluctant to leave the house when it is cold. The cold causes her pain and since she does not have her own car, she is dependent on public transport for further distances. She has been smoking for many years, although she knows full well that smoking is not good for her disease and that every year millions of people die miserably from smoking. She now wants to quit smoking and wants to be accompanied intensively as she knows from her previous attempts how difficult it is to quit smoking. It would be good to meet the counsellor regularly, but at the same time she finds it dissuasive that she has to make the long way to the smoking cessation clinic regularly for treatment, especially now in the cold season. The smoking cessation counsellor offers her that she can do part of the treatment via the Internet. Then she would not have to go through the cold so often. Alexandra gets along with computers and the Internet in everyday life. She likes the idea of carrying out the treatment partly in face-to-face at the clinic and partly web-based at home, and she is curious to see what such a blended treatment will be like and whether she will stick with it this time and ultimately succeed in stopping smoking.

SMOKING MACHINES AND SMOKING PEOPLE

After smoking steam engines, railways, electrical engineering and petrochemicals over the past 200 years, information and communication technology (ICT) is now - following the idea of long waves - the most important innovative technology (Papenhausen, 2008). After the start of the ICT ascent from the 1970s onwards, it spread increasingly to the health sector at the turn of the millennium (Della Mea, 2001). This development gave rise to the term e-health, which encompasses approaches at the intersection of medical informatics, public health and business and refers to health services and information provided or enhanced via the Internet and related technologies (Eysenbach, 2001). With the advent of e-health, we are currently also facing a sea change in the psychological treatment of mental health problems, as various applications of digital interventions have an impact on clinical practice, clinical services and the global spread of psychological treatments, with blended treatment - the subject of this thesis - being one of the most promising (Fairburn & Patel, 2017) and preferred (Schuster, Pokorny, Berger, Topooco, & Laireiter, 2018; Schuster, Topooco, Keller, Radvogin, & Laireiter, 2020).

The concept of blended treatment is still relatively new - at least it was when this research project started about six years ago in 2014. The first papers directly using the term “blended treatment” appeared around this time, with the Netherlands in particular leading the way (Kooistra et al., 2014; Mansson, Skagius Ruiz, Gervind, Dahlin, & Andersson, 2013; Postel, Witting, & Gemert-Pijnen, 2013; Ruwaard & Kok, 2015; van der Vaart et al., 2014a; Wilhelmsen et al., 2013). Blended treatment started with the idea of offering both face-to-face and web-

based interventions in one integrated treatment, thus overcoming their previous separation - either face-to-face or web-based - and as a result making care more customer-friendly, better quality and more targeted (Postel et al., 2013). This positive expectation went along with the consideration that blended treatment combines the “best of both worlds” (van der Vaart et al., 2014b; Wentzel, van der Vaart, Bohlmeijer, & van Gemert-Pijnen, 2016), as the strengths of one form of treatment should compensate for the weaknesses of the other (Barak, Hen, Boniel-Nissim, & Shapira, 2008; Erbe, Eichert, Riper, & Ebert, 2017; Kemmeren et al., 2016a; Postel et al., 2013; van der Vaart et al., 2014b; Wentzel et al., 2016). For example, personal attention by a professional in the case of face-to-face treatment could compensate for the lack of personal contact in the case of web-based treatment. In turn, one of the main features of web-based treatment is the possibility of being available anytime and anywhere, which could bridge the intervals between sessions in face-to-face treatment.

In the meantime, a variety of approaches to the implementation and research of blended treatment for mental and behavioral disorders can be found. For example, various disorders such as depression (Kooistra et al., 2014), anxiety (Bruinsma, Kampman, Exterkate, & Hendriks, 2016) or addictions (alcohol (Blankers, 2020), cocaine, marijuana (Carroll et al., 2008), opioids (Christensen et al., 2014), or in this project tobacco) are being treated. Different tools (e.g. web platforms, emails, SMS, APPs (Kemmeren et al., 2016b; Kleiboer et al., 2016)) and different mix ratios of the modes of delivery are used (e.g. mainly web-based (Harrington et al., 2012; Massoudi et al., 2017) vs. mainly face-to-face (Bruinsma et al., 2016; Mansson et al., 2013); or integrated vs. sequential (Harrington et al., 2012)). There are individual and group treatments (Schuster, Leitner, Carlbring, & Laireiter, 2017). And a distinction can be made between interventions that are more program-led (“Supervised digital treatment”) and those that are more clinician-led (Treatment by the clinician which incorporates digital interventions) (Fairburn & Patel, 2017). The blended treatment, which was the heart of this project, could be seen as an integrated, 50% face-to-face and 50% website based, clinician-led protocolized individual treatment for tobacco addiction (see below).

SMOKING ADDICTION

The relevance of tobacco addiction arises from the fact that – according to the World Health Organization (WHO) (WHO, 2019a) - the tobacco epidemic is one of the biggest public health threats the world has ever faced: Tobacco kills up to half of its consumers and this means more than eight million people every year (for the sake of comparison, this is about as much as wiping out Amsterdam once a month). More than seven million of these deaths are due to direct tobacco consumption, while about 1.2 million are due to the exposure of non-smokers to passive smoking (WHO, 2019a). The economic costs of tobacco consumption are considerable and include significant health costs of treating the disease caused by tobacco consumption and the loss of human capital through the

morbidity and mortality attributable to tobacco consumption (WHO, 2019a). Smoking addiction is more prevalent in specific often vulnerable subpopulations such as for example individuals in lower education and/or socioeconomic groups (Drope et al., 2018). About 80% of the world's 1.1 billion smokers live in low and middle-income countries, where the burden of tobacco-related diseases and deaths is highest (WHO, 2019a).

Yet even in high income countries such as the Netherlands, smoking is still the main cause of preventable illness and premature death (Van Laar & van Gestel, 2018): in 2016, 24.1% of people over 18 years of age in the Netherlands were smokers and about 19,500 people aged 20 years and older died in the Netherlands as a direct result of smoking. It should be noted that the actual smoking-related death rate is higher because the effects of passive smoking (second-hand smoke) have not been taken into account. Of the total burden of disease in the Netherlands, 9.4 % can be attributed to smoking.

SMOKING CESSATION

People who stop smoking greatly reduce their risk for disease and early death (Lushniak, Samet, Pechacek, Norman, & Taylor, 2014) and will have major immediate and long-term health benefits (WHO, 2019b, 2020). Among smokers who are aware of the dangers of tobacco and the benefits of quitting, most want to quit (WHO, 2019a). The Health Survey 2017 shows that 41.0% of Dutch smokers aged 18 years and older have made one or more attempts to stop smoking in the previous twelve months (Van Laar & van Gestel, 2018). Most Dutch smokers try to quit smoking on their own (Van Laar & van Gestel, 2018). However, smoking cessation treatment remains pivotal, because chances of quitting tobacco can more than double with the right support (WHO, 2019b).

In the Netherlands, there are clinical guidelines (Partnership Stop met Roken, 2009a, 2017) and standards (Partnership Stop met Roken, 2009b, 2019) for smoking cessations support, and in order to qualify for reimbursement of treatment costs, the executing counselors must be listed in the Dutch Quality Register of qualified smoking cessation counsellors. Smoking cessation treatments consist primarily of behavioral support, possibly supplemented by pharmacological treatment (Partnership Stop met Roken, 2009b, 2019). These guidelines and standards ultimately integrate the findings of years of worldwide research on smoking cessation. Yet the effectiveness of smoking cessation remains limited and the effort to develop new methods is still ongoing. One potentially effective approach to developing new methods may be to combine proven methods in a new way. One example of this approach is the combination of face-to-face and web-based smoking cessation treatment, known as blended treatment.

BLENDED SMOKING CESSATION TREATMENT

The intervention at the heart of this research project – the Blended Smoking Cessation Treatment (BSCT) – meets the Dutch standards mentioned above. Furthermore, BSCT covers the majority of evidence-based behavior change techniques for smoking cessation (Michie et al., 2013), such as for example goal setting, self-control measures, managing withdrawal, action planning or smoking registration. Furthermore, the treatment also includes pharmacotherapy and nicotine replacement therapy. It is a high-intensity treatment with a planned total treatment time of 230min within a six-month period with an expected quit date after about three months.

BSCT consists of five face-to-face sessions at the outpatient clinic and five Web-based sessions delivered via the online treatment platform www.rokendebaas.nl. It comprises both counselor-dependent and counselor-independent components. The counselor-dependent web-based components are interactive and rely on (asynchronous) communication (email, messaging) between counselor and patient. The counselor-independent web-based components such as for example the smoking diary are used by the patients on their own and in their own time, as these components are accessible online.

The characteristic feature of BSCT is a 50-50 balance for face-to-face and Web-based sessions – the focus of the treatment is not supposed to be on the face-to-face-mode nor on the Web-mode; in addition, face-to-face-mode and Web-mode alternate constantly. Patients always have a face-to-face session, then a Web-based session, then again face-to-face and so on.

USER EXPERIENCE | ADHERENCE | EFFECTIVENESS

The blended smoking cessation treatment (BSCT) described above and the question hovering over this new treatment as to whether this blend offers "the best of both worlds" was investigated by highlighting the themes of user experience, adherence and effectiveness. User experience (UX) refers to what people personally encounter while using systems and services (Law, Roto, Hassenzahl, Vermeeren, & Kort, 2009; Obrist et al., 2012; Roto, Law, Vermeeren, & Hoonhout, 2011; Roto et al., n.d.). UX is of interest because UX is one of the main elements to clarify the use of services by individuals in general (Liébana-Cabanillas, Muñoz-Leiva, Sánchez-Fernández, & Viedma-del Jesús, 2015) and eHealth services, such as blended treatment, in particular (Ramtohul, 2015). UX thus influences the extent to which the patient's behavior corresponds with the treatment recommendations (i.e. Adherence). And just as UX influences adherence, adherence in turn influences effectiveness, because adherence has been shown to be an indicator of treatment's acceptability and thus a determinant of treatment's effectiveness (Alterman, Gariti, Cook, & Cnaan, 1999; Fish et al., 2009; Sabaté, 2003; Westman, Behm, Simel, & Rose, 1997). Unfortunately, adherence

is low in cessation treatment in general (Kemmeren et al., 2016a) as well as in web-based treatment in general (Erbe et al., 2017). Patients often end treatment prematurely and do not complete tasks and exercises between sessions (Bosworth, 2010). The low adherence is problematic because - assuming a dose-response-relationship - patients are more likely to quit smoking if they are more exposed to the treatment (Sabaté, 2003). Ultimately, however, the effectiveness of the treatment is of course crucial. Does the treatment lead to better or at least comparable quit rates to the treatment offered so far? If BSCT were non-inferior (Hahn, 2012) to the established face-to-face treatment, it could enrich the range of treatments on offer due to secondary benefits such as for example less travel time and costs and free choice of treatment method.

AIM AND OUTLINE OF THIS THESIS

The themes described above were investigated in this research project as a collaboration between the following four organizations from the Enschede region in the Netherlands:

1. The Research Group Technology, Health & Care at Saxion University of Applied Sciences
2. The Centre for eHealth and Well-being Research at University of Twente
3. The Outpatient Smoking Cessation Clinic and the Medical School Twente at Medisch Spectrum Twente hospital
4. Tactus Addiction Treatment

In this thesis, we wanted to investigate whether a blended treatment offers “the best of both worlds” by focusing on user experience, adherence and effectiveness, with the following questions examined in detail:

- User experience
  - How is the patients’ user experience in a blended face-to-face and web-based smoking cessation treatment (BSCT) (Chapter 3: User Experience)?
- Adherence
  - How can adherence to BSCT be measured, how adherent are patients, and what predicts patients’ adherence (Chapter 4: Adherence - Measurement, Levels, and Predictors)?
  - How is the adherence to BSCT compared to a face-to-face treatment (F2F), and what predicts adherence to BSCT compared to F2F (Chapter 5: Adherence - Blended vs. Face-To-Face Treatment)?
  - How is the adherence to both modes of delivery (Web-mode; F2F-mode) of BSCT, and what predicts adherence to both modes (Chapter 5: Adherence - Blended vs. Face-To-Face Treatment)?
- Effectiveness
  - Is BSCT at least as effective as F2F in terms of abstinence rates, and are patients more satisfied with either treatment (Chapter 6: Effectiveness - Blended vs. Face-To-Face Treatment)?

To answer these questions, the results of specific sub-studies are presented in the following chapters.

Chapter 2 provides the study protocol, offering an overview of the randomized controlled trial (LiveSmokefree-Study), which forms the framework of the adherence and effectiveness studies. The background, objectives and research questions are described as well as the corresponding outcome measures, their measurement methods and instruments and the planned analyses.

Chapter 3 presents a qualitative study of the user experience (UX) of the Blended Smoking Cessation Treatment (BSCT), because UX has been shown as an important factor in explaining patients’ use of health care services in particular. We conducted in-depth interviews and applied Hassenzahl’s model of UX to describe the patients’ UX of BSCT in routine care to address the question what positive and negative experiences patients have with BSCT in general and with the F2F sessions and the Web sessions in particular. This study provides rich insights into blended treatment, identifies practical improvements and raises new questions - for example, what role hedonism plays in blended treatment.

Chapter 4 introduces the first study of adherence. We addressed the measurement, levels and predictors of adherence in BSCT by quantitatively analyzing the patients’ face-to-face and web-based activities during treatment. With this study we contribute to the research methodology in the field of blended treatment and tobacco control, by evaluating a novel instrument to assess adherence.

Chapter 5 continues with a second study on adherence by comparing the adherence and the predictors of adherence in BSCT with those of a comparable face-to-face treatment. In addition, we look at both treatment delivery modes within BSCT in detail and compare the adherence and the predictors of adherence in the face-to-face mode of BSCT with its Web mode.

Chapter 6 addresses the effectiveness of BSCT. This study provides the intermediate six-months analysis of an unblinded two-arm, parallel group, randomized controlled non-inferiority trial as described in the protocol article (Chapter 2). We compare abstinence rates of BSCT at 6 months after start of the treatment with a comparable face-to-face treatment to

find out if the new blended treatment is non-inferior to the traditional face-to-face treatment. Furthermore, we compare the patients' satisfaction with both treatments.

Chapter 7 presents the general discussion in which we summarize the results of the sub studies, make methodological considerations, consider implications for clinical practice and further research, and return to the question whether blending offers "the best of both worlds".

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ABSTRACT

BACKGROUND

Smoking cessation can significantly reduce the risk of developing smoking-related diseases. Several face-to-face and web-based treatments have shown to be effective. Blending of web-based and face-to-face treatment is expected to improve smoking cessation treatment. The primary objective of this study is to compare the prolonged abstinence rate of the blended smoking cessation treatment with the face-to-face treatment. Secondary objectives are to assess the benefits of blended treatment in terms of cost effectiveness and patient satisfaction, and to identify mechanisms underlying successful smoking cessation.

METHODS/DESIGN

This study will be a single-center randomized controlled non-inferiority-trial with parallel group design. Patients (n=344) will be randomly assigned to either the blended or the face-to-face group. Both treatments will consist of ten sessions with equal content held within 6 months. In the blended treatment five out of ten sessions will be delivered online. The treatments will cover the majority of behavior change techniques that are evidence-based within smoking cessation counseling. All face-to-face sessions in both treatments will take place at the outpatient smoking cessation clinic of a hospital. The primary outcome parameter will be biochemically validated prolonged abstinence at 15 months from the start of the smoking cessation treatment.

DISCUSSION

This RCT will be the first study to examine the effectiveness of a blended smoking cessation treatment. It will also be the first study to explore patient satisfaction, adherence, cost-effectiveness, and the clinically relevant influencing factors of a blended smoking cessation treatment. The findings of this RCT are expected to substantially strengthen the base of evidence available to inform the development and delivery of smoking cessation treatment.

TRIAL REGISTRATION

Nederlands Trialregister NTR5113. Registered 24 March 2015.

BACKGROUND

Killing nearly six million people a year, smoking tobacco is one of the biggest public health threats. Of the smokers who are aware of the dangers of tobacco the majority want to quit (WHO, 2014). Although a proportion of smokers quit without professional support (Malarcher, Dube, Shaw, Babb, & Kaufmann, 2011), counseling and medication can more than double the success rate (WHO, 2014). Success rates of smoking cessation treatments (5-months-after-treatment) range between 8,5% (minimal or no counseling or self-help) and 27,6% (intense counseling & medication) (Fiore, Jaén, Baker, & al., 2008), depending on (1) contact time and intensity, (2) number and length of sessions, (3) number and type of clinicians involved, and (4) number and type of counselling formats and interventions. A treatment comparable to the ones of this trial has shown to lead to a cotinine-validated prolonged 12 months` abstinence rate of 10% (based on intention-to-treat analysis) (Christenhusz 2006; Christenhusz , Prenger, Pieterse, Seydel, & van der Palen, 2012).

Traditionally, smoking cessation treatment is offered as face-to-face counseling. With the rise of the internet, web-based treatment offers an additional channel for effective smoking cessation (Civljak, Stead, Hartmann-Boyce, Sheikh, & Car, 2013). Nowadays face-to-face treatment and web-based treatment are usually offered separately. An integration of web-based and face-to-face treatments (blended treatment) is expected to combine the “best of both worlds” (van der Vaart et al., 2014) as this will allow the strengths of one to offset the weaknesses inherent in the other (Barak, Hen, Boniel-Nissim, & Shapira, 2008).

The weaknesses of face-to-face treatment that can be offset by the strengths of web-based treatment refer to (1) therapist drift; (2) patients’ no-show and (3) travel costs.

1. Face-to-face treatments often suffer from therapist drift (Mansson, Skagius Ruiz, Gervind, Dahlin, & Andersson, 2013). This drift can be reduced by the protocolled nature of web-based treatments, which have shown to lead to higher treatment integrity (Waller, 2009).
2. Patients’ no-shows result in time lost both for the counselors and the patients. In BSCT counselors can replace patients not showing up with online work, which can be planned flexibly as the process of online communication with the patients occurs asynchronously. Patients that miss a face-to-face session can still access their personal online dossier and continue treatment autonomously (e.g. psychoeducation, exercises, and summaries of counseling conversations). As both counselors and patients can use their time more efficiently this can result in offering treatment to more patients (Kemmeren et al., 2016).
3. Travelling to the smoking cessation clinic to attend a face-to-face meeting with the counselors is both time consuming and costly for the client. Web-based sessions do

not require showing up at the clinic during the normal business hours, because they can be done e.g. at home in the evening. This reduces work time lost as well as travel related costs for the patients (Kooistra et al., 2014; Mansson et al., 2013).

The weaknesses of web-based treatment that can be offset by the strengths of face-to-face treatment refer to (1) poor engagement of patients and (2) tailoring of interventions.

1. A common problem of web-based treatment is poor engagement of users due to the small amount of personal contact (Graham et al., 2013). Face-to-face treatment offers more personal contact and may therefor result in a higher commitment of the patients.
2. Web-based treatments are supposed to offer more tailoring (Civljak et al., 2013). Face-to-face treatment can offer greater flexibility in customizing interventions to the patients' needs by for example explaining therapeutic interventions or providing additional information for diagnostic purpose or case management (Mansson et al., 2013; Postel, Witting, & Gemert-Pijnen, 2013; Spek et al., 2007).

To the best of our knowledge there has been no research on the potential benefits of a blended treatment for smoking cessation. The primary objective of this research is to find out if a blended smoking cessation treatment (BSCT) results in non-inferior quit rates compared to a face-to-face treatment as usual (TAU). Secondary objectives are to assess whether

1. patients are more satisfied with BSCT;
2. BSCT reduces treatment costs;
3. there is link between quitting and adherence in BSCT;
4. there are moderators or mediators predicting treatment outcome; and
5. how the treatment can further be improved.

METHODS/DESIGN

The study will be a single center randomized controlled non-inferiority trial with a parallel group design.

STUDY POPULATION

The study population will consist of the patients of the outpatient smoking cessation clinic at Medisch Spectrum Twente (MST), Enschede, The Netherlands. These patients will be referred to the clinic by treating physicians of the hospital or by their GPs.

INCLUSION/EXCLUSION CRITERIA

Participants of this study will be smokers who admit themselves to the cessation clinic (indicating readiness to quit), who are at least 18 years old, who are currently daily smokers

(at least one cigarette/day), and who are able to both access websites and communicate by email (both verified during intake procedure by asking whether the participant has internet access at home, and a current email address). People who are not able to read or write in the Dutch language will be excluded from this study.

RECRUITMENT

Participant will be recruited from those patients that have signed up for smoking cessation treatment at the outpatient smoking cessation clinic. Based on earlier studies and the criteria for participation, we expect that a majority of patients will be eligible for this study. Participation in the study will be voluntary and patients will not receive any payment for participation.

RANDOMIZATION

Patients will be randomly assigned to either BSCT or TAU. Randomization will be performed at the individual level (allocation ratio 1:1) using QMinim Online Minimization (http://qminim.sourceforge.net/) (Saghaei & Saghaei, 2011). The minimization will be stratified according to: (1) level of internet skills (van Deursen, Courtois, & van Dijk, 2014); (2) level of nicotine dependence (A. N. Mudde, 2000)); and (3) the quitting strategy favored by the patient (stop at once, gradual change, scheduled reduced smoking; for details see below the description of the study intervention). The data used for the QMinim minimization will be collected using the baseline questionnaire, which will be filled in online by the patient at home.

BLINDING

The study will be an open label study, as it is self-evidently impossible (due to the nature of the treatment conditions) to blind the staff and patients that are involved.

STUDY INTERVENTION

BSCT will be a combination of face-to-face treatment combined with web-based treatment into one integrated smoking cessation treatment that can be delivered in conventional smoking cessation clinics (Kooistra et al., 2014; Postel et al., 2013). Both BSCT and TAU will be provided by the Outpatient Smoking Cessation Clinic (SRP), which is part of the Department of Pulmonary Medicine of MST hospital. The web-based interaction of BSCT – which patients will do e.g. at home - will make use of Tactus Addiction Treatment`s website http://www.rokendebaas.nl. Out of this web-based treatment five session have been adopted for the integration in BSCT (table 1). The SRP team consists of a pulmonologist and three qualified stop-smoking counsellors. The counsellors are registered on the Dutch Quality Register of qualified smoking cessation counsellors (http://www.kwaliteitsregisterstopmetroken.nl). Both treatments fulfil the requirements of the Dutch care module for smoking cessation (Partnership Stop met Roken, 2009) which is derived from the evidence-based Dutch

Guideline Treatment Tobacco Addiction (CBO, 2009).The costs of smoking cessation treatment will be reimbursed by the patient's health care insurance.

TAU is personalized to the patients' needs and contains flexibility in quitting strategies. To allow for comparability this flexibility is also integrated in BSCT. At treatment start the patients will be asked to favor one of three quitting strategies:

1. Stop at once: the patient sets a quit date, makes a preparation plan and stops abruptly on the quit date.
2. Gradual change: the patient selects daily activities and contexts in which smoking is habitual and step-by-step continues these activities smoke free (for example when reading newspaper, Facebook, reading email, drinking coffee); finally, the patient sets a quit date. Being already accustomed to a range of daily habits without smoking will make it easier for the patient not to relapse.
3. Scheduled reduced smoking (Cinciripini, Wetter, & McClure, 1997): the patient gradually decreases the number of cigarettes at regular intervals; at the start the patient does not smoke less but becomes used to a fixed schedule, and in subsequent phases the number of cigarettes will be gradually reduced (100%→75%; 75%→50%; 50%→25%) until the patient is ready to stop completely. This strategy systematically deconditions the cues. Although recent studies (Lindson-Hawley et al., 2016; Wilson & Md, 2016) suggest that gradual cessation strategies – such as scheduled reduced smoking - may be sub-optimal compared to abrupt cessation, gradual cessation is still superior to non-treatment (Cinciripini et al., 1997). Offering scheduled reduced smoking broadens the target group for the cessation clinic, as it also allows patients who are initially reluctant to quit abruptly to enroll. Further, as it is an established part of TAU in this clinical setting, gradual cessation needs to be included in BSCT as well.

Both BSCT and TAU will consist of 10 sessions with similar content spread over six months, with the frequency of sessions fading over time (six sessions within the first three months, four sessions within the final three months). Although participants may choose their preferred quitting strategy, this only marginally affects the content of the actual treatment that is delivered. Regardless of quitting strategy, the number and order of sessions is identical, as well as the effective components: the behavioral change techniques applied within sessions do not vary systematically. However, within the early sessions some differences may occur on a more detailed level within the BCTs (e.g. the timing of goal achievement within goal setting), due to quitting strategy.

All TAU sessions will take place at the SRP clinic while BSCT sessions will take place alternately face-to-face at the SRP (five sessions) and online (five sessions). This blended protocol resulted from a user centered design approach in which experts and counselors were involved in developing the most suitable mix of both delivery modes. The 50%-50% blend of face-to-face and web-based sessions results in a considerable substitution by web-based interaction, while at the same time maintaining the intensity of the full intervention.

As in TAU, BSCT consists of both counselor-dependent and counselor-independent components. The counselor-dependent web-based components of BSCT are interactive and rely on (asynchronous) communication between counselor and patient. The counselor-independent components such as psycho-educational content or the smoking diary are used by the patients on their own and in their own time. In TAU these components are provided in a paper manual that clients take home. In BSCT, these components are accessible online. As such, both treatments are equivalent with regard to both content and intensity. An additional benefit of BSCT, though, is that the content of previous counselor-dependent components remains accessible as email correspondence saved online.

Both BSCT and TAU will cover the majority of the behavior change techniques that are used within individual behavioral support for smoking cessation (Michie, Hyder, Walia, & West, 2011), including those techniques that have shown to be reliably associated with better quit outcomes (West, Walia, Hyder, Shahab, & Michie, 2010). The distribution of the main behavior change techniques and the distribution of the face-to-face and web-based session are shown in Table 1.

TABLE 1 .Distribution of the behaviour change techniques in the face-to-face and online session in BSCT and TAU

Session/week	Name (Code) of the main behavioural change techniques according to (Michie et al., 2011)	TAU	BSCT
Session 1, week 1 Goal setting	Provide information on consequences of smoking and smoking cessation (BM1) Provide rewards contingent on successfully stopping smoking (BM4) Identify reasons for wanting and not wanting to stop smoking (BM9) Facilitate goal setting (BS4) Prompt self-recording (BS6) Advise on stop-smoking medication (A1) Advise on/facilitate use of social support (A2) Build general rapport (RC1) Explain expectations regarding treatment programme (RC4)	Face-to-face	Face-to-face
Session 2, week 3 Measures for self-control	Provide feedback on current behaviour (BM3) Provide rewards contingent on effort or progress (BM7) Facilitate barrier identification and problem solving (BS1) Facilitate relapse prevention and coping (BS2) Prompt review of goals (BS5) Prompt self-recording (BS6) Advise on changing routine (BS7) Tailor interactions appropriately (RD1)	Face-to-face	Online

TABLE 1 continued.

Session/week	Name (Code) of the main behavioural change techniques according to (Michie et al., 2011)	TAU	BSCT
Session 3, week 5 Dealing with withdrawal	Provide feedback on current behaviour (BM3) Provide normative information about others' behaviour and experiences (BM5) Facilitate relapse prevention and coping (BS2) Prompt self-recording (BS6) Provide information on withdrawal symptoms (RC6) Provide reassurance (RC10)	Face-to-face	Face-to-face
Session 4, week 7 Breaking habits	Provide feedback on current behaviour (BM3) Provide normative information about others' behaviour and experiences (BM5) Facilitate barrier identification and problem solving (BS1) Facilitate relapse prevention and coping (BS2) Advise on changing routine (BS7) Advise on conserving mental resources (BS10) Advise on avoiding social cues for smoking (BS11) Advise on/facilitate use of social support (A2) Provide reassurance (RC10)	Face-to-face	Online
Session 5, week 9 Dealing with triggers	Provide rewards contingent on effort or progress (BM7) Facilitate relapse prevention and coping (BS2)	Face-to-face	Face-to-face
Session 6, week 11 Food for thought	Provide feedback on current behaviour (BM3) Offer/direct towards appropriate written materials (RC5) Elicit client views (RC8)	Face-to-face	Online
Session 7, week 14 Think differently	Provide feedback on current behaviour (BM3) Measure CO (BM11) Facilitate barrier identification and problem solving (BS1) Facilitate relapse prevention and coping (BS2) Prompt self-recording (BS6) Build general rapport (RC1) Elicit and answer questions (RC2)	Face-to-face	Face-to-face
Session 8, week 18 Do differently	Provide feedback on current behaviour (BM3) Facilitate barrier identification and problem solving (BS1) Facilitate relapse prevention and coping (BS2) Prompt self-recording (BS6) Tailor interactions appropriately (RD1) Build general rapport (RC1)	Face-to-face	Online
Session 9, week 22 Action plan	Provide feedback on current behaviour (BM3) Measure CO (BM11) Facilitate action planning/develop treatment plan (BS3) Build general rapport (RC1) Elicit client views (RC8)	Face-to-face	Face-to-face
Session 10, week 26 Closure	Provide feedback on current behaviour (BM3) Provide rewards contingent on successfully stopping smoking (BM4) Strengthen ex-smoker identity (BM8) Facilitate barrier identification and problem solving (BS1) Facilitate relapse prevention and coping (BS2) Facilitate goal setting (BS4) Set graded tasks (BS9) Advise on/facilitate use of social support (A2) Build general rapport (RC1) Offer/direct towards appropriate written materials (RC5) Elicit client views (RC8)	Face-to-face	Online

Codes: BM = Specific focus on behaviour (B) and addressing motivation (M); BS = Specific focus on behaviour (B) and maximising self-regulatory capacity/skills (S); A = Promote adjuvant activities (A); RC = General aspects of the interaction (R) focusing on general communication (C); RD = General aspects of the interaction (R) focusing on delivery of the intervention (D)

MEASUREMENTS

The time-points of the follow-up measurements are tied to the estimated stop-date, which is appropriate for aid-to-cessation trials (Hughes et al., 2003). The expected stop-date is three months after treatment start, which is later than in common cessation treatments where quitting usually is expected within one to three weeks. In total there will be four follow-up measurements with measurement 3 and 4 (9 months and 15 months follow-up) to be conducted at standard time points (i.e. 6 and 12 months after the expected stop-date):

1. 3 months after treatment start, expected stop-date, (3 months follow-up);
2. 6 months after treatment start, end of treatment and 3 months after expected stop-date, (6 months follow-up);
3. 9 months after treatment start, 3 months after end of treatment, 6 months after expected stop-date, (9 months follow-up); and
4. 15 months after treatment start, 9 months after end of treatment, 12 months after expected stop-date, (15 months follow-up).

A measurement schedule can be found in Table 2. The biochemical measurements will be done when the patient is at the hospital for a face-to-face session in week 1 (Exhaled CO; baseline/month 0), week 14 (Exhaled CO & Cotinine level; month 3) and week 22 (Exhaled CO; month 5). For the final biochemical measurement (Exhaled CO & Cotinine Level; month 15) which will take place 12 month after the expected stop date in month 3, the patient will have to return to the hospital. All other assessments will be done using online questionnaires which the patients will complete at home.

TABLE 2. Measurement schedule

Variables	Measurement at month					
	0	3	5	6	9	15
PRIMARY OUTCOME						
Cotinine level		X				X
SECONDARY OUTCOMES						
Nicotine dependence (Fagerström)	X			X	X	
MAP-HSS + smoking related complaints of smokers	X			X	X	X
Depression, anxiety and stress (DASS21)	X			X	X	X
Quality of Life (Euroqol 5D)	X			X		
Smoking status	X	X		X	X	X
Adherence						X
Costs						X
BASELINE PREDICTORS AND MODERATORS OF TREATMENT EFFECT						
Internet Skills	X					
Readiness to change	X					
Attitude	X			X	X	
Social Influence	X					
Self-Efficacy	X			X		
Alcohol/substance (mis)use	X			X		

TABLE 2 continued.

Variables	Measurement at month					
	0	3	5	6	9	15
DESCRIPTIVE VARIABLES						
Patient characteristics and medical history	X					
Smoking history	X					
Stop Smoking History	X					
OTHER INFORMATION OF INTEREST						
Evaluation of treatment		X		X	X	X
Exhaled carbon monoxide (CO) level	X	X	X			X

The CO measurements in the study will serve as a backup for the cotinine measurements. They will only be analyzed in case the saliva samples are not usable. This backup strategy has been chosen because CO measurements are part of the routine stop-smoking treatment. To keep the burden for the participating patients as low as possible the measurements are linked to the scheduled face-to-face sessions. As the last face-to-face session in both treatment groups usually takes place in week 22 this moment has been chosen for the measurement to prevent the patient from travel time/work time loss for an extra appointment because of the study.

During the informed consent procedure all participants will receive a patient information letter that outlines the burden of participation, including the online questionnaires. By stressing the importance of the online questionnaires, we try to increase patient commitment. During the trial, completion of the questionnaires will be checked after two weeks. Participants not completing the questionnaire will receive four weekly reminders: first twice via email, then twice by telephone. If a participant signals to be struggling with completing the questionnaire online, we will offer a paper version of the questionnaire, which will be sent including a return envelope.

INSTRUMENTS

Primary outcome

Cotinine level

The primary outcome parameter will be biochemically validated prolonged abstinence (Hughes et al., 2003) at 15 months from the start of the smoking cessation treatment. Saliva cotinine level will be measured as biochemical verification of abstinence only by those patients that report quitting smoking in the previous online questionnaires (Verification, 2002). Prolonged abstinence is defined as having salivary cotinine levels < 20ng/ml (Jarvis, Fidler, Mindell, Feyerabend, & West, 2008) that validate both the self- reported abstinence after the self-chosen stop date – usually three months after start - and the self-reported abstinence at 15 month follow-up. Patients not reporting abstinence or with a higher cotinine

level on any of these follow-ups will be regarded as smokers as well as patients who are lost to follow-up. A 0,5-1ml salivary sample will be collected for cotinine assessment by means of a Salivette (Sarstedt AG & Co., Nümbrecht, Germany). Under supervision, patients will have to chew on a cotton swab for one minute to stimulate the saliva flow rate. All saliva specimens will be frozen until assayed and transported to the laboratory for the determination of the cotinine level using a gas chromatography technique.

Secondary outcomes

Nicotine dependence

Fagerstroem Test for Nicotine Dependence (FTND) (Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991) is the most commonly used tool for the assessment of nicotine dependency. The scores obtained on the test permit the classification of nicotine dependence into five levels: very low (0 to 2 points); low (3 to 4 points); moderate (5 points); high (6 to 7 points); and very high (8 to 10 points). The instrument evaluates for example time from awakening to the day's first cigarette, smoking when bed-ridden with illness, and difficulty in refraining from smoking when prohibited.

MAP-HSS + smoking related complaints of smokers

The MAP-HSS is a ten-item health scale, which was adapted from the Opiate Treatment Index (Darke, Ward, Zador, & Swift, 1991). Each item is scored on a five-point Likert-type scale, ranging from 0 (complaint never present in the previous 30 days) to 4 (complaint always present in the previous 30 days), resulting in a total scale-score ranging from 0 to 40. In addition to MAP-HSS the patients will be asked to scale 16 typical smoking related complaints (for example cold hands and feet, cough, pale skin, pain in the lung). An overall score of physical complaints will be calculated by adding MAP-HSS and the additional smoking related complaints.

Depression, anxiety and stress (DASS-21)

The DASS21 (Antony, Bieling, Cox, Enns, & Swinson, 1998; Lovibond & Lovibond, 1995) is a consistent, valid and reliable set of three self-report scales designed to measure the negative emotional states of depression, anxiety and stress. Each of the three DASS scales contains seven items. Patients will be asked to use 4-point severity/frequency scales to rate the extent to which they have experienced each state over the past week. Scores for Depression, Anxiety and Stress will be calculated by summing the scores for the relevant items.

Quality of Life (Euroqol 5D)

The EuroQol-5D (EuroQol, 1990) is a generic quality-of-life (QoL) instrument which consists of 5 domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. There are three response alternatives for each domain. The EQ-5D index is obtained

by means of applying predetermined weights to the five domains. The EQ-5D index is a societal-based numerical quantification of the patients' health status which can range from 0 (death) to 1 (perfect health status). In addition to the five domains, EuroQol-5D also offers an overall rating for quality of life by means of a visual analogue scale (VAS). The VAS is a vertical line from worst (0) to best state of health (100).

Smoking status

Smoking status comprises self-reported smoking related variables such as quit attempts (>24h), number of relapses, or the amount of daily tobacco consumption (cigarettes, self-rolled cigarettes, cigarillos, e-cigarettes). All smoking status variables are based on a standardized questionnaire for Dutch tobacco research (A. Mudde, Willemsen, Kremers, & de Vries, 2006).

Adherence

In order to find out how the web-based application is used, real-time logdata will be collected to track individual use. These log files will be used for identifying user profiles and to gain insight into adherence to the application, usage patterns that emerge, and what elements of the application are used. This information will provide insight in how the application (both content and system) matches with its users. In addition, information about the type and number of BCTs taken from the patient's record, which is kept by the counsellor, will be analyzed to calculate the level of adherence.

Costs

All direct treatment-related costs generated by the care providers and the patients: Costs will be calculated based on hours spent by the counsellors (including for no shows), patients' travel costs, and maintenance of the web-based infrastructure.

Baseline predictors and moderators of treatment effect

Internet Skills

Internet skills will be measured using an online questionnaire based on conceptual definitions for internet skills (van Deursen et al., 2014). This conceptual definition includes two major skill areas (medium-related Internet skills and content-related Internet skills), which contain in total five minor skill areas. Medium-related Internet skills include operational (for example operating an Internet browser or a search engine) and formal (for example maintaining a sense of location when on the Internet) skills. Content-related Internet skills include informational (for example defining search options or queries), communication (for example searching, selecting, reaching and evaluating contacts online) and strategic (for example taking advantage of the Internet) skills. A 10 item questionnaire (Schols, 2013) will be used to measure internet skills with a 5-point Likert scale, resulting in a score range from 10 (unskilled) to 50 (highly skilled).

Readiness to change

Readiness to change will be measured using the algorithm to detect the stage of change in smokers (DiClemente et al., 1991). The expected stop moment (within 1 month versus within 2 or 3 months) offers the possibility to distinguish between the contemplation and preparation stage of change.

Attitude, social influence and self-efficacy

According to the ASE Model (de Vries, Dijkstra, & Kuhlman, 1988; Vries & Mudde, 1998) the intention to stop smoking is determined by three motivational factors: Attitude, Social Influence and Self-Efficacy. Attitude (Ajzen & Fishbein, 1975, 1980) refers to the overall evaluation of smoking cessation. Attitude will be measured with an indirect, belief-based scale for perceived pros (4 items: improved health for the patient, improved health for the patient's personal environment, lower risk of lung cancer, improved self-satisfaction) and cons (4 items: suffering withdrawal symptoms, missing smoking, less ability to relax, feeling bored). Social influence refers to three distinctive constructs: social norms, perceived behavior of others and direct support. It will be measured recording if the patient is stimulated to stop smoking by acquaintances, if his/her partners is a smoker and how many of his/her acquaintances are smokers. Self-Efficacy (Bandura, 1986) refers to the confidence in the ability to refrain from smoking in specific high-risk situations, i.e. the situations in which the quitter is tempted to relapse. It will be measured recording six typical relapse situations (e.g. stress or party). The three constructs of the ASE model will be measured using standardized questions developed by the former Dutch foundation STIVORO (Christenhusz, Pieterse, Seydel, & van der Palen, 2007; A. Mudde et al., 2006).

Alcohol and substance (mis)use

Alcohol (mis)use will be measured using the Five-shot questionnaire on heavy drinking (Seppa, Lepisto, & Sillanaukee, 1998). Only if a patient declares that he/she is consuming alcohol/substances at all, additional questions will be asked to keep the burden for the patient as low as possible. The additional questions will record the frequency and amount of alcohol consumption, feelings of anger and guilt related to drinking, and if the patient drinks in the morning to cope with hangover. Substance (mis)use will be measured asking for (recreational-)drug use in general. If the patient declares to use (recreational-)drugs additional questions will ask for type of (recreational-)drug and frequency and duration of use.

Descriptive variables

Patient characteristics and medical history

Demographical data (sex, age, nationality, cultural background, marital status, children, housing, education, source of income, main activity) will be collected using an online questionnaire. Medical history will be recorded from medical charts.

Smoking history

Smoking history will be measured using an online questionnaire from the longitudinal Vlagtwedde-Vlaardingen Study (1965 to 1990) (Jansen et al., 1999) recording the age of first smoking attempts and the numbers of years and number of cigarettes/day that the patient was smoking in each decade.

Stop Smoking History

Earlier attempts to stop smoking will be recorded using an online questionnaire asking: if there were earlier stop smoking attempts; when the last stop smoking attempt was; how long the non-smoking phase was; and when the last stop smoking attempt was, which was successful for more than 24 hours.

Other information of interest

Evaluation of treatment

Three months after start of the treatment, at the end of the treatment (six month after start) and during the follow-up measurements (9 and 15 month after start) patients will be asked to report their experiences with the different aspects of the treatment program. Patients can rate satisfaction with the program by grading all separate types of contact, assessing the overall contact with their counsellors, and reporting their own perception of improvements. In addition, they will be asked to report on adherence, results and benefits, gained insights, the use of co- interventions, and the use of NRT. Furthermore, they will be asked for improvement suggestions.

Exhaled carbon monoxide (CO) level

The measurement of exhaled carbon monoxide (CO) level provides an immediate, non-invasive method of assessing smoking status (Cropsey et al., 2014). A breath CO level of 5 ppm is taken as the cut-off between smokers and non-smokers (5ppm or higher=smoker, less than 5ppm=non-smoker). Breath CO monitoring will be performed using a piCo Smokerlyzer (Bedfont Instruments: Kent, UK), a portable CO monitor. The level of exhaled carbon monoxide (CO) level will be recorded because the CO measurement is already part of the treatment so that these data is easily available. Because the validation of the smoking cessation is done with cotinine tests (see above) the CO data will only be used if cotinine measurements are missing and to provide data for future research such as for example comparing different measurement techniques.

SAMPLE SIZE

For this RCT 344 patients will be needed. This is based on the following assumptions and calculations. Since we expect that BSCT will be at least non-inferior to TAU concerning prolonged abstinence, we conduct a non-inferiority trial. Furthermore, we expect BSCT to

be better at secondary factors such as costs, adherence and satisfaction. (Lesaffre, 2008). Based on previous studies involving smoking cessation treatment within the organization involved in this RCT (Christenhusz 2006; Christenhusz et al., 2012) and meta analyses (Fiore et al., 2008), a cotinine-validated prolonged 12 months` abstinence rate of 10% (based on intention-to-treat analysis) with TAU is expected. Based on the expected benefits of BSCT the estimated abstinence rate for BSCT is 15%. If BSCT leads to an abstinence rate of not lower than 5% it will be regarded as non-inferior. With a power of 80% and α of 0,025 172 patients per group are needed for this RCT (calculated with PASS). The 5% criterion is based on the three assumptions described below:

1. A validated prolonged abstinence rate of 5% may still be considered as superior to (1) a non-intervention condition which is estimated at a 1.4% abstinence rate and to (2) a 2.6% abstinence in a minimal intervention condition in clinical populations such as COPD patients (Hoogendoorn, Feenstra, Hoogenveen, & Rutten-van Molken, 2010).
2. In a worst-case scenario, BSCT patients will fail to use the web-based part of the intervention completely and adhere to the face-to-face component only. This would reduce their exposure to the intervention by 50% compared to full adherence to TAU. Assuming a linear dose-response relationship of intervention intensity and likelihood of abstinence the 10% abstinence rate estimated for TAU would then be reduced by 50% to a 5% abstinence rate.
3. Although a 5% abstinence rate is considerably lower than the estimated 10% in TAU, the secondary benefits of BSCT - such as client satisfaction - need to be taken into account. Thus, even at a lower effectiveness we expect that BSCT can still be the preferred treatment.

Based on the experience that approximately 360 patients per year start a cessation treatment at SRP, it is expected that recruitment, treatment and follow-measurements of the 344 patients needed for this RCT will take three to four years.

HANDLING OF STUDY DROPOUTS

If a subject is prematurely withdrawn or withdraws from participation in the study for whatever reason, the statistical analysis will be conducted following the intention-to-treat principle (Gupta, 2011), assuming that missing cases are at their baseline level. This will produce conservative estimates of smoking abstinence but will still allow for treatment outcomes that are based on the entire sample. Patients who fail to keep an appointment will be contacted and if possible, will be rescheduled for another appointment, ideally within seven days of the missed appointment.

DATA MANAGEMENT

The handling of personal data will comply with the Personal Data Protection Act in The

Netherlands. Data will be recorded using the two ways of data collection described below.

1. Data from the face-to-face contacts will be recorded on data collection forms and centrally collected at Medisch Spectrum Twente. The study data manager will record all the collected data in a Microsoft Access 2007 database.
2. The majority of data will be recorded by Tactus Addiction Treatment – a regional addiction care organization with experience in web-based treatment - using online questionnaires which will be offered to both treatment groups. Individual patients and counsellors will have a login with username and password secured by Secure Sockets Layer to the application. All data transferred between the patient's personal computer and the application will be encrypted and sent via the https protocol. All data will be encrypted and stored on servers in secure data centers within the Netherlands. Daily backups of the server will be made to ensure further data security.

DATA ANALYSIS/ STATISTICAL METHODS

Baseline characteristics will be displayed as means with standard deviations (SD) or medians with interquartile range (IQR) for continuous variables depending on the distribution of the variable; categorical variables will be displayed as counts with corresponding percentages. Differences between the two treatment groups in terms of continuous variables will be tested by the independent T-test or the Wilcoxon rank sum test, depending on the distribution of the variable. Differences in categorical variables will be tested by the Chi-square test or the Fisher exact test.

The non-inferiority between BSCT and TAU in salivary cotinine validated 12 months' prolonged abstinence rate will be analyzed by calculating the 95% confidence interval of the observed difference in the abstinence rate and by comparing that to the previously defined non-inferiority margin of 5%.

To assess whether BSCT leads to a decrease in treatment costs compared to TAU, an incremental cost-effectiveness ratio (ICER) will be calculated using treatment costs and abstinence rate.

To assess whether BSCT leads to improved satisfaction among patients and counsellors compared to TAU, satisfaction (based on the middle and long-term evaluation) will be tested between the two groups by applying the independent T-test or the Wilcoxon rank sum test.

Both baseline predictors - moderators of intervention effect - and dynamic predictors - mechanisms through which effects occur - will be tested using moderator and mediator analyses (Preacher & Hayes, 2004, 2008), including all potential co-variates such as nicotine dependence, cognitive determinants (for example attitude and self-efficacy), medical conditions and mental states (for example depression and anxiety), adherence and internet skills.

Whether the level of adherence to BSCT is related to prolonged abstinence will be tested by the independent T-test or the Wilcoxon rank sum test.

All analyses will be performed based on the intention-to-treat principle and will be performed in SPSS version 20.0.

DISCUSSION

To the best of our knowledge, this RCT will be the first study to examine the effectiveness of a blended smoking cessation treatment compared to purely face-to-face treatment. It will also be the first study to explore patient satisfaction, adherence, cost-effectiveness, and active ingredients of a blended smoking cessation treatment. The main three strengths of the LiveSmokefree Study are:

1. The blended smoking cessation treatment explored in this study was developed by a team in which all relevant stakeholder actively participated;
2. it demonstrates high ecological validity involving the heterogeneous population of regular patients of an outpatient smoking cessation clinic; and
3. it includes a long term biochemically validated follow-up assessment.

Main objective is to test whether face-to-face-smoking cessation treatment can be substituted by a less demanding and more patient-friendly blended treatment with similar outcomes. As our clinical experience with blended smoking cessation treatment evolves, this trial will contribute to the understanding of the influence of blended treatment on both the stop smoking process and the patient's experience. The conduct of this trial and its findings will substantially strengthen the evidence base regarding new delivery modes of smoking cessation treatment. If blended smoking cessation treatment is shown to be non-inferior on effectiveness while offering secondary benefits, then dissemination to clinical practice should be warranted. Such secondary benefits may be lower treatment costs and higher user friendliness.

However, there are also limitations in this study. First, by allowing participants in both arms to opt for one of three different quitting strategies (stop at once, gradual change, scheduled reduced smoking), heterogeneity is introduced within the treatment. As allocation to the treatment groups is stratified on this criterion, however, all three quit strategies will be distributed equally over both groups and therefore not affect the internal validity of this

trial. As a result, the main objective of this trial, i.e. comparing two modes of delivery of a treatment with identical content and intensity, is safeguarded. External validity may be somewhat impeded, though, as most cessation interventions in previous trials do not display such a flexible, preference-based, quit approach. To explore this issue, sub-analyses of program effects among participants within each quit strategy will be considered, depending on sufficient sample size within subgroups. Alternately, moderation by quit strategies or by preference-based personalization requires testing in a more complex trial design with multiple study arms in future research.

Despite this obvious limitation, the personalized quitting strategy can also be considered a strength of the treatment, as it broadens the treatment to a larger target group and increases the potential reach among smokers.

Another limitation that will merit discussion of the practical relevance is the rather inflexible approach of blending in the treatment (five web-based sessions and five face-to-face sessions in a fixed sequence and with equivalent content) that is used to allow for comparability. This inflexible approach may limit the potential of blending. Blending web-based and face-to-face intervention could - in extremis - lead to a flexible exchangeability of all intervention components, which would foster a treatment that is highly tailored to the patient's needs and abilities. This would allow both the counsellor and the patient to choose a preferred blend of web-based or face-to-face delivery, while maintaining efficacy. Future studies should explore such benefits of flexibly blended treatment options. Recruitment of patients started in May 2015.

List of abbreviations

BSCT	Blended Smoking Cessation Treatment
FtF	Face-to-face
GP	General practitioner
ICER	Incremental cost-effectiveness ratio
IQR	Interquartile range
MREC	Medical Research Ethics Committee
MST	Medisch Spectrum Twente hospital
QoL	Quality of life
RCT	Randomized controlled trial
SD	Standard deviation
SRP	Outpatient Smoking Cessation Clinic of Medisch Spectrum Twente (Dutch: Stoppen-met-Roken-Poli)
TAU	Treatment as usual
VAS	Visual analog scale

Ethics approval and consent to participate

In line with the Dutch Medical Research Ethics Committee (MREC) guidelines [16] the study was approved by the accredited MREC Twente (P14-37/NL50944.044.14) and subsequently by the Board of Directors of Medisch Spectrum Twente hospital. Before initiation, the study was registered with the Dutch Trial Registration (NTR5113). All patients will have to sign an informed consent form before they will be randomized.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

LS, MEP, MGJBK, and MGP identified the study questions and designed the study and its measuring instruments. LS is principal investigator and wrote the first draft of this manuscript. LS, MEP, MGJBK, MGP and SBA edited this manuscript. LS, MEP and MGJBK revised the manuscript. All authors approved the final version of this manuscript for publication.

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User Experience

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ABSTRACT

BACKGROUND

Blended web-based and face-to-face (F2F) treatment is a promising electronic health service because the strengths of one mode of delivery should compensate for the weaknesses of the other.

OBJECTIVE

The aim of this study was to explore this compensation by examining patients' user experience (UX) in a blended smoking cessation treatment (BSCT) in routine care.

METHODS

Data on patients' UX were collected through in-depth interviews (n=10) at an outpatient smoking cessation clinic in the Netherlands. A content analysis of the semantic domains was used to analyze patients' UX. To describe the UX, the Hassenzahl UX model was applied, examining 4 of the 5 key elements of UX from a user's perspective: (1) patients' standards and expectations, (2) apparent character (pragmatic and hedonic attributes), (3) usage situation, and (4) consequences (appeal, emotions, and behavior).

RESULTS

BSCT appeared to be a mostly positively experienced service. Patients had a positive-pragmatic standard and neutral-open expectation toward BSCT at the treatment start. The pragmatic attributes of the F2F sessions were mostly perceived as positive, whereas the pragmatic attributes of the web sessions were perceived as both positive and negative. For the hedonic attributes, there seemed to be a difference between the F2F and web sessions. Specifically, the hedonic attributes of the web sessions were experienced as mostly negative, whereas those of the F2F sessions were experienced as mostly positive. For the usage situation, the physical and social contexts were experienced positively, whereas the task and technical contexts were experienced negatively. Nevertheless, the consequential appeal of BSCT was positive. However, the consequential emotions and behavior varied, ultimately resulting in diverse combinations of consequential appeal, emotions, and behavior (positive, negative, and mixed).

CONCLUSION

This study provided insight into the UX of a blended treatment, and the results support the expectation that in a blended treatment, one mode of delivery may compensate for the weaknesses of the other. However, in this certain setting, this is mainly achieved in only one way: F2F sessions compensated for the weaknesses of the Web sessions. As a practical conclusion, this may mean that the Web sessions, supported by the strength of the F2F sessions, offer an interesting approach for further improving the blended treatment. Our theoretical findings reflect the relevance of the aspects of hedonism, such as fun, joy, or happiness in the UX, which were not mentioned in relation to the Web sessions and were only scarcely mentioned in relation to the F2F sessions. Future research should further investigate the role of hedonistic aspects in a blended treatment, and if increased enjoyment of a blended treatment could increase treatment adherence and, ultimately, effectiveness.

INTRODUCTION

BLENDED TREATMENT

Health care is undergoing a sea change driven by the progress in digital technology (Fairburn & Patel, 2017). One of the interesting innovations is blended treatment—a combination of the Web-based and face-to-face (F2F) therapy (Kooistra et al., 2014; Wentzel, van der Vaart, Bohlmeijer, & van Gemert-Pijnen, 2016). Blended treatment is a promising electronic health (eHealth) service because it is expected that the strengths of one mode of delivery will compensate for the weaknesses of the other (Barak, Hen, Boniel-Nissim, & Shapira, 2008; Erbe, Eichert, Riper, & Ebert, 2017; Kemmeren et al., 2016; Postel, Witting, & Gemert-Pijnen, 2013; Siemer et al., 2016; van der Vaart et al., 2014; Wentzel et al., 2016). For example, it is the strength of F2F treatment to be able to provide the personal attention of a professional that could compensate for the lack of F2F contact in Web-based treatment. In turn, one of the unique features of Web-based care is the accessibility, anytime and anywhere, which could compensate for the time in between F2F sessions when patients need support. Until now, there has been no final definition for blended treatment (Erbe et al., 2017; Wentzel et al., 2016), and it is offered in various formats. The literature on blended treatment mentions different modes of delivery (eg, mainly Web-based (Harrington et al., 2012; Massoudi et al., 2017), mainly F2F (Bruinsma, Kampman, Exterkate, & Hendriks, 2016; Mansson, Skagius Ruiz, Gervind, Dahlin, & Andersson, 2013), 50-50 blend of Web-based and F2F (Kooistra et al., 2016)), different orders of F2F- and Web-based treatment (e.g., sequential (Harrington et al., 2012) or integrated (Siemer et al., 2018; Siemer et al., 2016)) and different tools for its use (such as platforms, emails, short message service, text messaging, and apps (Kemmeren et al., 2016; Kleiboer et al., 2016). The intervention in this study is an integrated 50-50 blend of F2F treatment and treatment via a Web platform.

USER EXPERIENCE AND BLENDED TREATMENT

One of the main elements clarifying the individual's use of services in general (Liébana-Cabanillas, Muñoz-Leiva, Sánchez-Fernández, & Viedma-del Jesús, 2015) and eHealth

services, such as blended treatment, in particular (Ramtohul, 2015), is the user experience (UX). UX refers to what people personally encounter, undergo, or live through while using, interacting with, or being confronted passively with systems (Roto et al., n.d.). Systems can denote products, services, and artifacts—separately or combined in one form or another—that a person can interact with (Roto, Law, Vermeeren, & Hoonhout, 2011).

Usually, the term UX refers to products, services, and objects that a person interacts with through a user interface (Law, Roto, Hassenzahl, Vermeeren, & Kort, 2009). However, for this study, we widened the scope of this term to explore the UX of a service (i.e., blended treatment) that alternately uses computer-mediated communication *via* a user interface and F2F communication in counselling sessions.

Although a number of studies have examined the blended treatment (Siemer et al., 2018), little is known about the patients' UX specifically with blended treatments. An evaluation study (n=7) of a blended cognitive behavioral treatment for major depression (Kooistra et al., 2016) showed that while the patients' pretreatment expectations were mainly neutral and some skeptical patients found it hard to start with the Web-based sessions, most patients appeared to have positive attitudes toward the blended treatment afterward. Another study (Wilhelmsen et al., 2013) (n=14) on internet-based cognitive behavioral therapy for depression supported by short F2F consultations found that a sense of relatedness in terms of feeling connected to the therapist and being able to identify with the Web-based treatment may increase patients' adherence to the blended treatment. Both the studies suggest that the elements of patients' UX, such as expectations, usability, and identification, play a role in adherence to a blended treatment and should further be explored.

PATIENTS' USER EXPERIENCE

For the patients' perspective on the blended care treatment, Hassenzahl's model of UX from a user's perspective was adapted (Hassenzahl, 2003, 2008, 2018; Law et al., 2009). This process-oriented constructivist model defines five key elements and their functional relations (Figure 1). Basically, the model states that while getting in contact with the *features* of a product or service, a process is triggered, in which the user constructs the UX (this is illustrated by the grey arrow in Figure 1). In the beginning, the user constructs—moderated by the person's *standards and expectations*—an *apparent character* of the product or service. Moderated by the specific usage *situation,* the apparent character will then finally mediate a number of *consequences*.

The features of the service (in this case the blended treatment) are selected and combined by the treatment developers independently of the patients that ultimately follow the treatment. Since the features are not constructed by the users, the product features only play a minor

role in this study. In turn, the focus is placed on the patients' response to the treatment's features to explore the UX from the user's perspective in a narrower sense. This means that the UX from a user's perspective is built based on only four of these five key elements: (1) the patient's standards and expectations, (2) the apparent character, (3) the usage situation, and (4) the consequences. In the following paragraphs, each key element is described and illustrated by examples of how it applies to the blended treatment in this study.

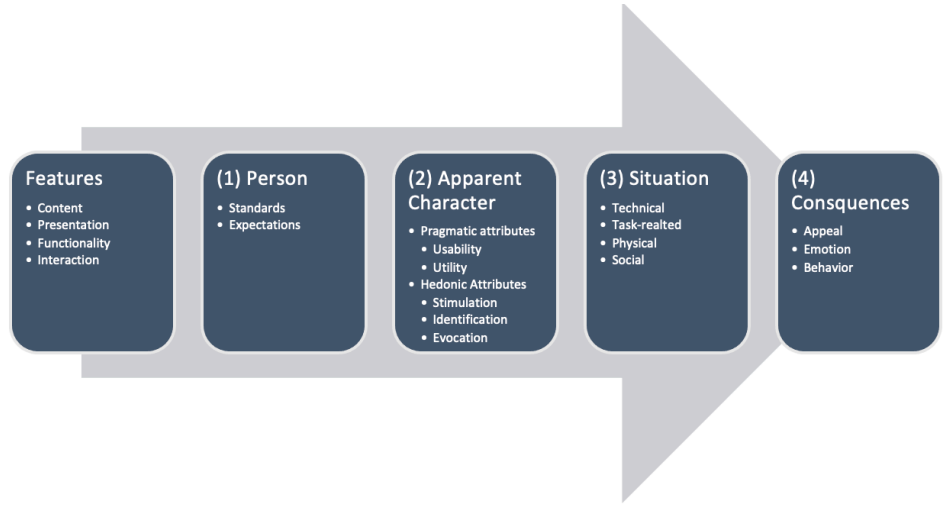

FIGURE 1. Key elements of the ux model (adapted from hassenzahl, 2003, 2018)

Features

The *features* of a product or service refer to its *content*, *presentation*, *functionality*, and *interaction* (Hassenzahl, 2003, 2018). The content of the treatment of this study—Blended Smoking Cessation Treatment (BSCT)—refers, for example, to the behavioral change techniques for smoking cessation (Michie, Hyder, Walia, & West, 2011) that comprises BSCT. The presentation refers to the clinical surrounding as BSCT is part of the routine care setting of a hospital. Functionality and interaction refer to the F2F and Web-based sessions, which offer synchronous interactions with the counselor (e.g., functions, such as providing feedback on behavior and building rapport) and asynchronous counselor-independent interactions with the Web-based system (e.g., functions, such as self-recording of smoking behavior *via* a Web-based smoking diary). More details about the study intervention are provided below in the Methods section.

Person

The patients' *standards* and *expectations* are based on their experiences with the other

services (Hassenzahl, 2003, 2018) with which the patient can compare BSCT. If a patient compares BSCT with, for example, earlier experiences in health care, smoking cessation support, F2F treatment, or use of computers and internet, the patient may start BSCT with a subjective standard, such as “using the computer for treatment is too difficult for me,” or with an expectation, such as “blended treatment will be more comfortable because I can partly do treatment at home.”

Apparent Character

When confronted with a service, an apparent character is constructed by the user. The apparent character is a cognitive structure representing *pragmatic* and *hedonic* attributes (Hassenzahl, 2003, 2018). Pragmatic attributes refer to the *utility* (e.g., “supporting,” “useful”) and *usability* (e.g., “clear” and “easy to use”) of a service, such as BSCT. Hedonic attributes of BSCT refer to *stimulation* (e.g., “novel and interesting” and “makes me think”), *identification* (e.g., “my style”), and *evocation* (e.g., “reminds me of filling in tax forms”).

Situation

The usage situation moderates the consequences of the apparent character (Hassenzahl, 2003, 2018) and refers to the *technical*, *task-related*, *physical*, and *social* contexts. These situations are different between patients and over the course of the treatment, especially for the Web-based sessions. For example, filling in a smoking diary while being on your own in a silent surrounding may result in different consequences than doing this in the living room with a partner and children around you.

Consequences

The fit of the apparent character and the usage situation leads to three consequences: *appeal*, *emotions*, and *behavior* (Hassenzahl, 2003, 2018). For patients, BSCT, for example, may appeal as “fine” while feeling “satisfied” and “adhering to the treatment.”

AIMS OF THIS STUDY

As UX has been shown as an important factor in explaining the behavior of a user in general (Castañeda, Muñoz-Leiva, & Luque, 2007), and patients’ use of health care services in particular (Haun et al., 2014), the aim of this study is—from a UX point of view – to explore whether in blended treatment the strength of one mode of delivery may compensate for the weaknesses of the other. By applying Hassenzahl’s model of UX to qualitatively describe the patients’ UX of BSCT in routine care, the question what positive and negative experiences patients have with BSCT in general and with the F2F sessions and the Web sessions in particular will be addressed. This research will contribute to a deeper understanding of the facilitators and barriers to blended treatment, which will provide new insights for both scientific research on blended treatment and its improvement in clinical practice. It is

expected that the application of the findings on UX elements in furthering the development of blended treatment will lead to better treatment outcomes.

METHODS

STUDY INTERVENTION

BSCT is a clinician-led intervention (Fairburn & Patel, 2017) which combines F2F and Web-based treatment delivered in routine care settings at the Outpatient Smoking Cessation Clinic (Stoppen met Roken Poli [SRP]) of the Department of Pulmonary Medicine at Medisch Spectrum Twente Hospital in Enschede, The Netherlands. BSCT is derived from the Dutch Guideline Tobacco Addiction (CBO, 2009), fulfilling the requirements of the Dutch care module for smoking cessation (Partnership Stop met Roken, 2009). The treatment is based on both the F2F treatment as usual at SRP (Christenhusz , Prenger, Pieterse, Seydel, & van der Palen, 2012; Pieterse, van der Palen, & Hagens, 2009) and Web-based treatment at Tactus Addiction Treatment (www.rokendebaas.nl). A team of clinical experts from both the organizations developed BSCT, striving for a 50-50 mix with constant alternating of F2F and Web-based treatments by replacing five of the usual ten F2F sessions with appropriate Web-based sessions. This treatment design decision was made based on the randomized controlled trial (LiveSmokefree study (Siemer et al., 2016), which compared the effectiveness of BSCT with F2F treatment. The order, planning, mode of delivery, and main content of the BSCT sessions is shown in Table 3. The details of BSCT have been described in earlier papers (Siemer et al., 2018; Siemer et al., 2016). To provide an impression of the look and feel of the Web interventions, Multimedia Appendix 1: Screenshots of the Web-Sessions of BSCTshows screenshots of the Web sessions of BSCT.

TABLE 3. Order, planning, mode of delivery, and main content of the blended smoking cessation treatment sessions

Session	Week	Mode of delivery	Content
1	1	Face-to-face	Goal setting
2	3	Web-based	Measures for self-control
3	5	Face-to-face	Dealing with withdrawal
4	7	Web-based	Breaking habits
5	9	Face-to-face	Dealing with triggers
6	11	Web-based	Food for thought
7	14	Face-to-face	Think differently
8	18	Web-based	Do differently
9	22	Face-to-face	Action plan
10	26	Web-based	Closure

SETTING AND PARTICIPANTS

The current study is a substudy of the LiveSmokefree study—a single-center randomized controlled noninferiority trial with parallel group design, which examines the effectiveness of BSCT as compared with F2F treatment. The inclusion criteria for the LiveSmokefree study were (1) aged 18 years or older, (2) willing to quit smoking, (3) current daily smoker (at least one cigarette a day), and (4) speaking/reading/writing Dutch.

A purposive sample (n=10) of the participants from the blended arm of the LiveSmokefree study (Siemer et al., 2016) that had already ended the treatment was selected, striving for a heterogeneous mix of patients regarding the characteristics (Table 5) that were expected to influence the patients' UX (i.e., age, sex, educational level, adherence, counselling, and quitting success). For recruitment, the patients were called and invited by the research assistants to participate in the UX study. The participation was voluntary; patients had to sign an informed consent form and received no incentives.

ETHICS

Both the LiveSmokefree study and this substudy on patients' UX were approved by the accredited Medical Research Ethics Committee Twente (P14-37/NL50944.044.14). The LiveSmokefree study was registered in the Dutch Trial Registration (NTR5113).

DATA COLLECTION

Qualitative data about the patients' UX was collected by in-depth semi-structured interviews. The interview guide (Multimedia Appendix 2: BSCT UX Interview Guide (Dutch)) was developed following the key elements of the UX (Hassenzahl, 2003, 2018) to elicit both the patients' standards and expectations toward BSCT, the apparent character of BSCT (usability, utility, stimulation, identification, and evocation), the usage situation (technical, tasks, physical, and social), and the consequences (appeal, emotions, and behavior). Additional interview questions were created from a clinical perspective addressing practicalities (e.g., intake procedure, treatment procedure, and adherence) and ideas for the improvement of current BSCT.

The interviews were conducted by the first author (LS) between October 2016 and March 2017. Because LS is not a Dutch native speaker, he was supported by trained Dutch research assistants to avoid possible ambiguities and linguistic misunderstandings. On the date of the interview, the interviewees were picked up from the waiting area of the SRP and led to a neutral meeting room. After receiving permission for audio recording, the interviewer read a written introduction, which emphasized that the patient was invited to recall and describe ("tell stories") their UX. After this briefing, a general stimulus ("Can you, first of all, tell us what your experiences with the blended treatment are? We would like to hear all the events and experiences that were important to you.") was used to start. Interviews followed a detailed written interview guide (Multimedia Appendix 2: BSCT UX Interview Guide (Dutch)), but were open-ended in nature, allowing the interviewers to ask probing questions and to follow up on interesting topics and experiences related to BSCT.

The audio-recordings were transcribed verbatim by trained research assistants following the guidelines for data preparation and transcription, as described by McLellan et. al. (McLellan, MacQueen, & Neidig, 2003) and were subsequently analyzed using the qualitative data analysis software ATLAS.ti Version 8.3.1 (ATLAS.ti Scientific Software Development GmbH).

AUXILIARY DATA

The data regarding the patients' age, sex, education level, internet skills, nicotine dependence, and counselor (Table 5) were acquired from the LiveSmokefree study database, for which the data were collected using a Web-based questionnaire that the patients completed at the beginning of the treatment. A detailed description of the variables and their measurements can be found in the protocol article of the LiveSmokefree study (Siemer et al., 2016). The patients' characteristics were reported as medians with IQRs or as numbers using SPSS version 24.

The data about adherence and smoking status (Table 5) were acquired from a dataset build in 2018 for a paper on adherence to BSCT (Siemer et al., 2018). Based on 18 patient activities that reflect the course of the treatment (e.g., attending a F2F session or completing a Web-based task), an adherence score ranging from 0 (nonadherent to any activity after the first treatment session) to 18 (adherent to all activities) was calculated for each patient. The patients' adherence rates were reported as medians with IQR using SPSS version 24. Based on a 60% threshold for both the F2F sessions and the Web sessions (Siemer et al., 2018). the patients were classified as adherent or nonadherent to BSCT. Questions regarding adherence were also asked in the interviews (see above), which might have led to different assessments (e.g., patient #25). To examine the self-reported smoking status (stopped smoking: Yes/No), data from both the in-depth interviews and the follow-up Web-based-questionnaires of the LiveSmokefree study 6-month after the treatment start were used. In case the interview and questionnaire data contradicted each other, the interview data were considered superior.

CODEBOOK DEVELOPMENT

Based on the semi-structured interview guide, content analysis was used to analyze all the interviews. The codebook was developed by two research team members (LS, SA), building on the interview guide and the research goals related to the clinical setting (e.g., ideas for improvement of BSCT) (DeCuir-Gunby, Marshall, & McCulloch, 2011)). The codes

were grouped in semantic domains and intercoder agreement was analyzed per semantic domain using the intercoder analysis feature of Atlas.ti 8.2.4. The disagreements were discussed, and the codebook was revised until acceptable agreement (Krippendorff c-α-binary 0.650-0.928) for each semantic domain was achieved. The codes, their description, and the intercoder agreement per semantic domain are displayed in Table 4.

TABLE 4. Codes, code description, and intercoder agreement per semantic domain

Semantic Domain Code - Description	Krippendorff's c-α-binary
User Experience	0.676
ux bsct - User experience with the blended treatment - Phrases in which the patient describes an experience during the treatment which he/she also combines with an evaluation and/or emotion (e.g. "good", "bad", "frustrating") Only the phrases that refer to the blended treatment, Not the ones referring only to F2F, or WEB or others (episodic and/or cumulative UX)	
ux f2f - User experience with the F2F parts of BSCT - As ux bsct, but only referring to the F2F parts of BSCT	
ux web - User experience with the WEB parts of BSCT - As ux bsct, but only referring to the WEB parts of BSCT	
ux others - User experience that cannot be related to other UX Codes - As above, but only if not referring to the other three UX codes	
System	0.650
motivation to follow bsct - Motivation to continue the treatment - The motivation to adhere to the treatment which are closely related to properties of the treatment itself, e.g. supporting elements of the treatment,	
presence of counselor online - What the patient thinks about the counselor while he/she is in the web-based part of the treatment - Description and ideas about what the patient thinks about the counselor while he/she is using the Web-based parts of the treatment, e.g. "having the counselor in mind while using the tools" or "feels like filling in a tax declaration"	
User	0.726
earlier treatment experience - Prior experience in F2F and WEB treatment/counselling - This is about treatment/counseling IN GENERAL, for prior experience in smoking cessation use code „smoking cessation experience. All experience in BSCT comparable treatment including treatment and counseling in health- or behavior related topic in an f2f, Web-based and/or group setting.	
expectation towards bsct - Expectation at treatment start - What patients expected when they were informed to be included in BSCT (anticipated UX)	
health status - Additional information about health and mental status - Additional information about health and mental status which is not closely related to the motivation (use Motivation quitting OR Motivation BSCT)	
it experience - Experience in using digital technology for communication - How the patient describes himself/herself in the use of computers, tablets, mobiles etc. for communication	
mood during smoking cessation - Moods/emotions related to quitting - Description of moods and emotions related to quitting smoking. (only if not explicitly related to BSCT - use UX-codes for these)	
motivation for smoking cessation - Motivation to quit or to stay abstinent - The motivation to quit and/or to stay abstinent which are not closely related to aspects of the treatment, but more related to e.g. smoking, health, family.	
smoking cessation experience - Experience in smoking cessation treatment - Earlier experience in smoking cessation AND current experience in smoking cessation which is not related to the current treatment	
Context	
physical context - Information about the physical context - Additional information about the physical context (e.g. housing situation, travel time) which is not closely related to the motivation (use Motivation quitting OR Motivation BSCT)	

TABLE 4 continued.

Semantic Domain Code - Description	Krippendorff's c-α-binary
Context	0.780
social context - Information about the social context - Additional information about the social context (e.g. partner, friends, family) which is not closely related to the motivation (use Motivation quitting OR Motivation BSCT)	
task context - What patients think about the structure and freedom during treatment - If not directly related to Motivation or UX	
technical context - information about the technological context - Information about the technological context such as computers, laptops, internet connection. Use only if phrase is not referring to Motivation or UX	
Structural	0.928
Improvements - Ideas and recommendations for further improvement of BSCT	
Intake - How the patients were informed before start of the treatment - Phrase of patients in which they describe the quality of the intake procedure and which are helpful for improvement of the treatment (do not mix up with Expectation)	
name of the treatment - Phrases of the patient in which he/she calls or describes BSCT in his/her own words in a "striking" expression	
patient characteristics matching bsct - Characteristics of users that increase matching between treatment and user - Phrases of patients in which he/she describes characteristics of users that best match with BSCT, e.g. "you need to be computer-literate"	
Procedures - Additional information about the procedures of the treatment - Phrase of patients in which they describe the procedures of the treatment and which are helpful for improvement of the treatment, but which are not closely related to the UX	
Miscellaneous	0.744
Advantages - Phrases in which the patient summarizes advantages of BSCT	
Disadvantages - Phrases in which the patient summarizes disadvantages of BSCT	
preference of treatment mode - Which kind of treatment the patient would prefer next time or advise to others - Phrases in which the patients evaluate the modes of the treatment by telling which mode of treatment he/she would go for next time or he/she would advise to others	
miscellaneous	

PARAPHRASING AND REGROUPING

After coding, all coded Dutch quotes were paraphrased in English by LS and collected in a table[2]. Applying Hassenzahl's model of UX from a user's perspective (Hassenzahl, 2003, 2018), the semantic domains of the codes were revised by linking the codes to the four of the five key elements, which form the UX from a user's perspective: (1) patients' standards and expectations; (2) apparent character (pragmatic attributes: usability, utility; hedonic attributes: stimulation, identification, and evocation); (3) usage situation (physical, social, technical, task); and (4) consequences (appeal, emotion, behavior). Finally, the UX was described for each key element distinguishing as far as possible between BSCT in general (i.e., the experience of BSCT as a whole) from the two modes of delivery (i.e., the F2F sessions and the Web sessions). Furthermore, in describing the UX, an attempt was made to make a distinction between the positive and negative UX, which is based on the idea that UX is a "primarily evaluative feeling (good/bad) while interacting with a product

2 Since this table is very extensive and cannot be adequately reproduced in the format of a thesis printed on paper, it is not included in this thesis. The table can be viewed in the online version of the article (link: https://formative.jmir.org/2020/6/e14550/).

or service" (Hassenzahl, 2008). Ultimately, we summarized the variety of consequences in three kinds of combinations of consequential appeals, emotions, and behavior.

RESULTS

OVERVIEW

In the following, the patient characteristics are presented first. Then, the positive and negative statements for each key element are described. As far as possible, this is done first for BSCT in general and then for the F2F and Web sessions. It is to be noted that the analysis and presentation methods were clarified after the interview phase, and the statements were not always available in every area.

PARTICIPANTS

Patients' characteristics are shown in Table 5. The median age of the patients was 59.0 years (IQR: 43.0-68.8), and the majority were males (7/10). Half (5/10) of the patients' educational level was lower than vocational education and training. The median internet skill level (range 10-50, higher numbers indicate higher skills (Siemer et al., 2016)) was 38.0 (IQR: 35.5-40.0), and the median nicotine dependence (Fagerström range: 0-10, higher numbers indicate higher dependency (Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991)) was 5.5 (IQR 3.8-7.0).

TABLE 5. Purposive sample

Characteristics	Randomization number									
	10	12	14	25	27	34	53	75	106	509
Age (years)	77	54	68	71	37	45	60	65	37	58
Sex (male; female)	m	m	m	f	f	m	m	f	m	m
Education level	L[a]	M[b]	M	L	L	M	L	M	L	M
Internet skills[c]	28	34	37	38	38	46	36	40	40	39
Fagerström[d]	5	7	4	6	7	4	3	2	7	6
#Adherence F2F[e]	3	4	6	5	2	3	5	2	8	2
#Adherence Web[f]	3	2	8	2	0	3	6	9	7	2
#Adherence BSCT[g]	6	6	14	7	2	6	11	11	15	4
Adherence F2F[h]	N	N	Y	Y	N	N	Y	N	Y	N
Adherence Web[i]	N	N	Y	N	N	N	Y	Y	Y	N
Adherence BSCT[j]	N	N	Y	N	N	N	Y	N	Y	N
Counselor[k]	A	B	B	B	B	A	A	C	C	B
Stopped smoking[l]	Yes	No	Yes	No	No	No	Yes	No	Yes	No

[a]L: lower than vocational education and training.
[b]M: vocational education and training or higher.
[c]Internet skills: range 10-60; higher number indicates better skills.
[d]Fagerström: nicotine dependence; range 0-10; higher numbers indicate higher nicotine dependency.
[e]#Adherence F2F: adherence to face-to-face (F2F) sessions, range 0-8, based on the 8 activities belonging to F2F sessions; higher number indicates higher adherence.
[f]#Adherence Web: adherence to Web sessions, range 0-10, based on the 10 activities belonging to Web sessions; higher number indicates higher adherence.
[g]Adherence BSCT: adherence to blended smoking cessation treatment (BSCT) in general, sum of #Adherence F2F and #Adherence Web, range 0-18; higher number indicates higher adherence.
[h]Adherence F2F: categorical classification of adherence to the F2F sessions based on a 60% threshold (Y= adherent; N=nonadherent).
[i]Adherence Web: categorical classification of adherence to the Web sessions based on a 60% threshold (Y= adherent; N=nonadherent).
[j]Adherence BSCT: categorical classification of adherence to BSCT in general based on a 60% threshold (Y= adherent; N=nonadherent).
[k]Counselor: who carried out the treatment.
[l]Stopped smoking: self-reported abstinence.

PATIENTS' STANDARDS AND EXPECTATIONS

In general, the patients approached BSCT mostly with a positive-pragmatic standard and a neutral-open expectation. None of the patients had followed a blended treatment or a Web-based treatment before. Therefore, their standards and expectations were based mainly on earlier experiences with F2F sessions, with earlier stop smoking attempts, and with ICT use in general. Only one patient (#34) used health-apps (Mindfulness, Stoptober). However, most of the patients (7/10) had received F2F counseling before, participated in a group therapy (#34), or were familiar with mindfulness (#34, #53).

For *F2F sessions*, positive standards predominated. Patients said, for example, that "Human touch is important" (#75), quitting is easier with F2F support ("with help stopping will be easier" [#53, #14]), F2F treatment is "ideal," and it "adapts to your competencies" (#12). One patient, however, considered that it "can be hard if you dislike the counselor" (#14).

Building amongst others on *earlier stop smoking attempts*, patients had the standard that the quitting success may depend on themselves (reporting, e.g., "Stopping you have to do for yourself." [#12]; "Treatment only makes sense if you have the will to stop" [#14]; quitting is "more a mental than a physical problem" [#27]; "You have to be strong" [#27]; or "You just have to do the things" [#53]), on missing support ("With help stopping will be easier" [#53, #14], and on stress ("Relapses are caused by stress" [#10, #34, #75]).

For *ICT-use in general*, while being familiar with using ICT (e.g., searching the Web, using email/WhatsApp), the majority of patients showed a pragmatic standard "Computer is a tool" (#509, #75); "I am not a computer freak" (#12); "Computer is not my way" (#10); or "I am neither a forerunner nor a left behind" (#25). Only one patient (#34) reported that he "personalizes his mobile." Most patients also emphasized that they do not prefer computer-mediated communication over F2F communication because it "leads to misunderstandings" (#53), "it is easier to cheat online" (#34, #12), "it is easier to do sloppy" (34), "online information is not as important as written on paper" (#25), or "I do not trust internet information" (#509).

Three of the patients (#106, #27, #25) reported that they use mobile devices (smartphone, tablet) more often, for example, "I use the laptop less since I have a tablet" (#25) or "I prefer mobile over PC" (#27).

Referring to *BSCT in general*, most patients (#106, #34, #27, #75, #25) described their *expectations* as "neutral" or "not clear," while some (#53. #34, #10) emphasized to expect support from BSCT, saying, for example, that they want the counselor to be "a driving force" (#10) or that they expect "to get more grip on smoking cessation" (#34). One patient (#14) remarked that BSCT "is new and sounds interesting."

APPARENT CHARACTER OF BLENDED SMOKING CESSATION TREATMENT

While being confronted with BSCT and moderated by their standards and expectations, the apparent character of BSCT that the patients constructed, seemed to be both positive and negative. The *pragmatic attributes* (*usability* and *utility*) were experienced mostly positive while the *hedonic attributes* (*stimulation*, *identification*, and *evocation*), especially for the Web sessions, tended to be negative.

Pragmatic Attributes of Blended Smoking Cessation Treatment

BSCT's pragmatic attributes (*usability* and *utility*) were experienced as good. However, some patients also criticized pragmatic aspects of BSCT, especially of the Web sessions, which indicated possibilities for further improvements.

USABILITY

Most patients experienced the *usability of BSCT in general* as positive, reporting, for example, that the "intake was good" (#75, #10 ,#14), "there have been no problems" (#509), "everyone was kind" (#34) "everything was clear and easy to use" (#53), "all was quite logical" (#14), the "treatment was picked up well" (#53, #27, #10), "BSCT parts connected to each other" (#106, #75, #14), and that "the intervals between sessions were fine" (#53). One patient (#14) reported "less travelling" (Note: BSCT patients only had to attend 5 F2F sessions at the clinic, compared with 10 F2F sessions in the F2F treatment as usual) as an advantage of BSCT, while another patient (#10) found that "still having to travel to the hospital at all" is a disadvantage. Further negative aspects of usability reported were the "long waiting list" before treatment start (#14, #12) (Note: regular waiting time before treatment start was around two months), "the long waiting times" in the waiting area before start of a F2F session (#14), that it was "not clear where to turn to outside the office hours" (#14), that "intervals between sessions were too long" (#10, #25), and that "not everything was explained in detail" (#25) and that the patient was "surprised about the order of the sessions" (#25).

The *usability of the F2F sessions* was experienced as "easy" (#25) or as "easier than web" (#27). Yet some patients criticized "that the counselor did not have enough time" (#12, #10, #14) or that the sessions were "slow and time consuming" (#27, #14).

Six patients (#509, #106, #53, #27, #75, #14), experienced the *usability of Web sessions* as "easy to use," while three patients (#34, #10, #25) reported the opposite ("not easy to use"). The patients criticized that the Web sessions were "too time demanding" (#509, #106), there was "a lot of repetition" (#10, #53, #27, #14), they "did not get immediate response" (#14), they "did not receive online assignments" (#27), and the "login would have been easier if you do not have to remember your password" (#27). Furthermore, two patients (#509, #106) reported that they did the smoking registration on paper before doing it on the Web because "it was simpler" (#106). However, this was "double work" (#106). Yet the patients liked "to be notified about new Web content automatically" (#75), that "emails and phone calls raised awareness" (#34), that "filling in forms online was handy" (#34), and "online saved time" (#25).

UTILITY

With regard to the *utility of BSCT in general*, the patients experienced the utility as positive, finding that "all BSCT parts were helpful—some more, some less" (#53), BSCT "matched my quitting process" (#53), "all has been discussed" (#106), "there was progress" (#106), BSCT "offered support" (#27), or "Web only would not have offered what I needed" (#75).

The *utility of the F2F session* was experienced as positive by most patients (7/10) also. Patients reported that F2F "offered flexibility" (#75) as "I could talk to the counselors about all of my problems" (#509), "all has been discussed" (#14), that with F2F "it was easier to ask questions" (#14), F2F "you got direct answers" (#14), F2F "stimulated more than web" (#10), and F2F "with medication was better than medication only" (#106). The counselors "reinforced" (#53, #25), "stimulated" (#53, #14, #10), "offered support" (#53, #25, #14), "shared good metaphors" (#53), and "explained everything very well" (14). Three patients experienced the F2F session as not useful, saying that the counselors "did not offer enough support" (#34, #27, 12), "did not reinforce" (#12), "did not motivate" (#12), "did not discuss all alternatives" (#34), and "asked too much questions" (#27).

For the *utility of the Web sessions, there were both positive and negative experiences*. Some patients had a predominantly negative experience saying that "reporting *via* Web was too time demanding" (#509), that Web "offered too much information" (#106), that Web "did not match my quitting process" (#27, #14), that "a computer does not answer" (#14) and that Web "does not work for me" (#75). Furthermore, ideas for improvement were reported, such as "an App would be better than web" (#34) and other services should be

included, such as “short reinforcements *via* WhatsApp, emails, in-between sessions, video instructions, helpdesk, chat support, short instructions” (#34) and “audio information” (text to speech) (#27). However, patients also reported positive experiences saying that the Web “offered support in difficult moments” (#53), Web “offered tips” (#53), and “it was good to have information available online” (#27, #14, #34).

Hedonic Attributes of Blended Smoking Cessation Treatment

For the hedonic attributes (*stimulation*, *identification*, and *evocation*), BSCT was experienced both positively and negatively. While some patients felt *stimulated* by BSCT, others reported being demotivated. Especially for the Web sessions, most patients reported low *identification*. Also, the Web sessions *evoked* mostly negative comparisons and induced several ideas for improvements.

STIMULATION

Patients reported both positive and negative stimulation by *BSCT in general* and rather low stimulation referring to the *F2F sessions* and *Web sessions*.

For *BSCT in general*, patients—on the one hand—felt stimulated to “quit smoking” (#14), to “discuss costs of smoking” (#12), to “think” (#106, #34), to “dig deeper” (#509), or to “look back” (#75). Patients also reported that the carbon monoxide measurements during the F2F sessions stimulated quitting (#53, #12). On the other hand, patients reported that “BSCT did not offer new things” (#34) or was “not interesting” (#14), and that certain interventions (i.e., dealing with tempters) were “not new” (#25). Furthermore, patients were demotivated by “always the same questions” (#27), by “digging too deep” (#27), and by contradictory goals (quitting smoking vs weight reduction) (#27).

For the *F2F sessions*, patients said that the “counselor had no impact” (#27, #12, #14, #25). However, some patients (#12, #509, #34) reported that they were reinforced by the counselors to use the Web sessions.

For the *Web sessions*, one patient said, that Web “broadened your awareness” (#75), whereas the majority of patients reported no or low stimulation saying that “online won’t get through to me” (#53, #34, #14, #25), “online exchange with the counselor did not affect extraordinary” (#25, #509), and to be demotivated by the Web sessions (#10, #509) or computer use (#106).

IDENTIFICATION

For *BSCT in general* patients could identify linking to individual features, such as “perseverance” or “self-control.” However, for the Web sessions, most patients reported low identification. The ones showing higher identification with the Web sessions did this by referring to personal contact with the counselor. Patients found it easier with the *F2F sessions* than the *Web sessions* of BSCT.

Related to *BSCT in general,* patients reported that BSCT linked to individual features, such as “perseverance” (#75), “self-control” (#75), “the ability to work based on reading and writing” (#75), “IT-skills” (#10), and “age” (#10). However, one patient (#27) reported that she “felt treated like a child” and that she “lost her rhythms.”

For the *F2F sessions* patients reported that these “felt more familiar” (#106), that patients liked “the F2F sessions the most” (#53) and “talking to the ladies” (#10) (Note: by this the male patient (#10) refers to the female counselors).

For the *Web sessions,* most patients reported low identification, saying, “I don’t feel like it much” (#106) or “not to like online” (#106, #10), that “online is not my style” (#12, #75, #10, #25), to “prefer on paper” (#25), or being “too stupid for IT” (#10). One patient (#75) showed a higher identification with the Web sessions, emphasizing “Web I did for myself,” “I know why I did Web,” and “I understood the process.” In turn, she criticized saying that “online did not give the opportunity to make it more personal” (#75). Three patients reported that the Web parts supported their personal contact with the counselor, mentioning that *via* Web parts “I had contact with her” and “they knew something about me” (#509), that “during the F2F sessions it became clear that the counselor reads the Web content“ (#25), that “I had the idea that it is used on the other side” (#53), and that “you knew there is someone behind it” (#34). In turn, three patients reported that “you didn’t know who has written the content” (#15), that “computer did not talk to you” (#12, #14), and that “you did not get the feeling that there is a human being on the other side” (#12).

EVOCATION

For the *Web sessions,* the patients reported several negative comparisons, such as “Web was like handling a machine, because you are not sitting opposite to each other” (#106), Web sessions were like “bookkeeping” (#53, #34, #14), like “a manual” (#53), like “filling in tax forms” (#10), and like “paper” (#27).

SITUATION

For the usage situation, mostly the *technical* context had a negative impact on the UX. Especially the *Web sessions* depended on the technical factors, which were criticized. Furthermore, referring to the *task* context of *BSCT in general*, some patients reported not having enough time for the treatment. Both the *physical* and the *social* context were described as mostly positive.

Technical

For the technical situation, the patients referred to the *Web sessions*, criticizing by saying that Web "did not work on iPad" (#34, #10, #25, #75). Although the patients had been informed at start of the treatment that the software for the Web session could not be used on tablet computers, they would have preferred to use tablets because the "Tablet is always on, Laptop not" (#34, #75, #14, #25) and tablet "is more comfortable" (#10), or because they (#10, #25) moved from laptop to tablet during BSCT. Furthermore, for the use of computers for the Web sessions, the patients criticized by saying that they "had to start up the laptop, which takes time" (#106, #34, #14).

Task

Referring to tasks, patients reported not to have enough time for the BSCT "because of other tasks" (#509) or "because of family tasks" (#106), or to feel "sometimes stressed—sometimes relaxed" (#27).

Physical

For the *F2F sessions*, the patients reported little about the physical usage situation, mentioning only "that I live close to the hospital" (#25) and "that the treatment took place in the old building, which was not a nice place" (#34, #27) (Note: Between the patients treatment and the interviews the department moved to a new building).

For the *Web sessions*, the patients shared more information about the physical usage situation reporting that they did the Web sessions at "my own home office" (#25, #509), in a "hobby room upstairs, which is a nice place" (#10), "upstairs, where it is quite hot in the summer" (#14), "with the laptop at the dining table with wife and children around me" (#53), "in the kitchen" (#106), and "with laptop lying on the bed in the sleeping room" (#509).

Social

For the social situation during *BSCT in general*, most patients reported feeling supported by the family, saying that everyone "supported" (#53, #25) and "complimented" (#53), that "family motivated stopping" (#106) and "nearly no one in our family smokes" (#14), that "my partner stimulated" (#509, #10), "offered incentives" (#14, #53), "accompanied" (#14), "gave feedback on better health conditions" (#53) and "does not smoke" (#509), and that "children supported" (#27), "children were positive about quitting" (#53) and "my son also quit" (#14). One patient said he (#25") "lives alone" and "did not tell much about BSCT"; she reported that "everyone was sceptic of the quitting success." One patient (#27) reported that "her partner did not support," "questioned the Web sessions," and broke "the agreement to smoke outside only."

For friends and colleagues, the patients reported that "none of my friends smoke" (#10), "no one smokes inside" (#14), and that "colleagues also have positive experiences with cessation treatment" (#53). Furthermore, one patient emphasized that he "stimulates others to quit smoking" (#10).

CONSEQUENCES

Overall, *BSCT in general* had a positive *appeal*, while *emotions* (eg, "satisfaction") varied. Again, there was clear distinction between the *F2F sessions* and the *Web sessions*. Similar to the emotional consequences, the behavioral consequences (*adherence*, *quitting*) also varied, ultimately resulting in diverse combinations of consequential appeal, emotions, and behavior.

Appeal

For six patients (#106, #53, #27, #75, #14, #25), *BSCT in general,* appealed to be "good." The patients reported that BSCT was a "mix of talking and reading" (#14) and it "offered variety" (#75). The "shared information both F2F and Web was fine" (#106) and "Web only would not have been so easy" (#53). F2F sessions and Web sessions were "quite different" (#34); "sometime F2F was better—sometimes Web was better" (#14) and "Web was an extension of F2F" (#53). One patient (#27) emphasized the medical treatment saying "Champix was good."

The *F2F sessions* mostly appealed to be "good." The patients reported that the F2F sessions were "fine" (#509) or "finer than web" (#106) and that the F2F sessions were "most important" (#53) or "most important at treatment start" (#34). One patient (#12) emphasized "that only F2F touches your heart" and that he would go for F2F "100% in all facets." However, one patient (#27) said that the F2F sessions were "whiny." For the counselors, one patient (#27) described her counselor as "nice," while another patient (#34) said that his counselor had a "stiff posture" and that she was "annoying," "pedantic" and "cumbersome." For the *Web sessions*, the majority of patients reported a negative appeal, saying that the Web sessions "yielded nothing" (#509, #75, #14), were "a lot" (#509, #27), "cumbersome" (#106), "boring" (#34, #27), "tiring" (#27), "nonsense" (#12, #10), and "dead" (#10). However, one patient (#75) said that "Web was nice" while others—also referring to positive appeal—reported that the Web sessions could be done "comfortable at home" (#34) and that Web was "a serious matter" (#25), although she would not go for "Web only."

Emotion

Emotional consequences varied—some patients were satisfied with *BSCT in general*, some not. Again, there was a distinction between *F2F sessions* and *Web sessions*, but not as clear as for the appeal.

While two patients (#34, #25) said that they were not satisfied with *BSCT in general*, three patients reported to be satisfied (#27, #10) or "thankful" (#106). Furthermore, referring to negative emotions about BSCT in general, patients reported "feeling abandoned, left alone" (#12), "tension and the need to relax physically" (#75), and "contradictions between quitting smoking and weight reduction" (#27). One patient said that the F2F sessions and Web sessions stimulated "the same moods" (#25). The mood during the *F2F sessions* was "good" (#53, #27), while *Web sessions* were experienced as "unpleasant" (#27) and "making me nervous" (#34). One patient reported to feel "guilty because I did not stick to appointments" (#27).

Behavior

During the interviews, three patients (#14, #53, #25) reported that they *adhered* to *BSCT in general,* doing both the F2F sessions and the Web sessions. One of them (#14) said he "could have stopped after four sessions" because he was "sure not to need it in the future." However, he continued BSCT "to do the counselors and researchers a favor." Five patients (#106, #34, #27, #10, #25) reported that they found the *Web sessions* "sloppy." Furthermore, one patient (#27) mentioned that she "forgot about some of her sessions."

Based on the auxiliary data (Table 5), medium adherence to *BSCT in general* (range 0-18, higher number indicate higher adherence) was 6.5 (IQR: 5.50-11.75). Based on a 60% threshold for both the *F2F sessions* and the *Web sessions* (Siemer et al., 2018), three patients (#14, #53, #106) were classified as adherent to BSCT in general. One patient (#75) was classified as adherent to the Web sessions but not to the F2F sessions, while another patient (#25)—one of the patients who reported to be adherent to BSCT in general during the interview—was classified as adherent to the F2F sessions but not to the Web sessions. Five patients (#509, #34, #27. #12, #10) were classified as nonadherent, because they neither adhered to the F2F sessions nor to the Web sessions.

Based on the interviews and the auxiliary data, four patients (#10, #14, #106, #53) reported successful *quitting*. One (#106) mentioned that "I had no problems because I had medication (Champix)" and "I threw away my last shags." The other one (#53) mentioned that he told himself "Never again!" and "Enough!" (Basta!), and that "he saved money for the holidays with his family." Two patients (#75, #509) reported that they reduced smoking during BSCT.

COMBINATIONS OF CONSEQUENTIAL APPEAL, EMOTIONS, AND BEHAVIOR

The variety of consequential appeals, emotions, and behavior could be summarized in three types of combinations: "positive," "negative," and "mixed" consequences.

Three patients (#14, #53, #106) experienced "positive" consequences. BSCT appealed to

be good and they felt "satisfied"/"thankful," adhered to the treatment and quit smoking.
On the contrary, another three patients (#12, #34, #509) experienced "negative" consequences: The Web sessions appealed negative ("nonsense," "boring," and "yielded nothing") and BSCT in general resulted in negative emotions (abandoned/not satisfied). Ultimately, they did not adhere to the treatment and did not quit smoking.

Mixed consequences: Three (#25, #27, #75) of the four remaining patients did not quit smoking, while one (#10) did. Interestingly, BSCT in general appealed "good" to the nonquitters (#25, #27, #75) while—for the quitter (#10) at least, the Web sessions appealed to be "nonsense." Although two of the nonquitters (#25, #75) reported negative emotions ("tension"/"not satisfied"), these two patients at least partly adhered to BSCT (#25 adherent to F2F sessions; #75 adherent to Web sessions). In turn, the third nonquitter (#27) reported positive emotions ("satisfied") but did not adhere at all.

To the remaining quitter (#10), although the Web sessions appealed to be "nonsense" and he did not adhere to BSCT in general, he reported positive emotions ("satisfied") and ultimately quit smoking.

DISCUSSION

PRINCIPAL FINDINGS

This study aimed to provide insight in the UX of a blended treatment. In the light of this study, the expectation that the strength of one mode of delivery can compensate for the weaknesses of the other in blended treatment, can be partially supported because the F2F sessions compensated for the weaknesses of the Web sessions so that BSCT in general was mostly experienced positively.

Our study described the UX of a BSCT using Hassenzahl's key elements of UX from a user's perspective (Hassenzahl, 2003, 2018). Overall, BSCT in general appeared to be a mostly positively experienced service. Patients had a positive-pragmatic standard and neutral-open expectation toward BSCT in general at treatment start, and the pragmatic attributes of the F2F session were mostly perceived as positive while the pragmatic attributes of the Web sessions were perceived as both positive and negative. For the hedonic attributes, there seems to be a difference between the F2F and Web sessions. Specifically, the hedonic attributes of the Web sessions were experienced mostly negative while the hedonic attributes of the F2F sessions were mostly positive. For the usage situation, the physical and social context was experienced positively while the task and technical context was experienced negatively. Nevertheless, the consequential appeal of BSCT in general was

positive. However, the consequential emotions and behavior varied, ultimately resulting in diverse combinations of consequential appeal, emotions, and behavior (positive, negative, and mixed).

Although patients' pretreatment expectations toward BSCT were neutral and the Web sessions appealed negative, overall BSCT in general appeared to be positively experienced afterwards. This is in line with an evaluation study (n=7) by Kooistra et al (Kooistra et al., 2016) of a blended cognitive behavioral treatment for major depression. However, our study provides a more differentiated insight in why the Web sessions were appraised negatively. Applying Hassenzahl's distinction between pragmatic and hedonic attributes (Hassenzahl, 2018), our findings suggest that while patients experienced the pragmatic attributes (usability, utility) of the Web sessions in general as more positive, the negative hedonic attributes (stimulation, identification, and evocation) of the Web sessions led to a combination of negative consequences, such as negative appeal, negative emotions, and low adherence.

Interestingly, although the hedonistic gap made the Web sessions appeal negatively, the overall BSCT was experienced positively. This could support the assumption that in blended treatment the strength of one mode (i.e., F2F) may compensate for the weaknesses of the other (i.e., Web) (Barak et al., 2008; Kemmeren et al., 2016). This is further supported by our findings about relatedness and identification, which are in line with a qualitative study (n=14) by Wilhelmsen et al (2013) (Wilhelmsen et al., 2013) on the internet-based cognitive behavioral therapy for depression supported by short F2F consultations. Three of our patients that adhered to BSCT and ultimately quit smoking showed rather low identification with the Web sessions but had positive appeal and emotions toward BSCT in general, especially toward the F2F sessions. This positive overall appraisal may have cancelled out the negative appeal of the Web sessions.

We mainly found that the F2F sessions compensated for the weaknesses of the Web sessions. Yet three patients reported that the Web sessions influenced their personal contact with the counselor positively. Although the Web sessions mostly had a low identification and a negative appeal, the Web sessions supported the F2F sessions because these patients felt more related to the counselor. However, even though the Web sessions may have supported the F2F sessions, it should be noted that none of the patients indicated that the Web sessions compensated for the F2F sessions. It remains undecided if this is because there was no need for compensation as the F2F sessions were overall positive, or that the Web sessions were not able to compensate. It should also be taken into account that the routine care in the hospital was not Web based, the patients were of older age, and did not have an affinity for the internet (although they reported to have sufficient internet skills), and

the patients' preferences for modes of delivery were not taken into account as they were not free to choose for BSCT because they were included in a randomized controlled trial. These factors may additionally explain the low positive impact of the Web sessions.

The emotional and behavioral consequences varied, ultimately resulting in three types of combinations of appeal, emotions (e.g., satisfaction), and behavior (adherence, quitting): "positive," "negative," and "mixed." These types can be used to work on UX profiles that can support further development of blended care and improve the matching between the treatment and patient (Wentzel et al., 2016).

IMPLICATION FOR FUTURE RESEARCH AND CLINICAL PRACTICE

Further work needs to be done to investigate how the integration of F2F and Web treatments can be carried out to ultimately increase the effectiveness and efficiency of a blended treatment. This study provides a hint to explore this question by emphasizing the relevance of hedonic attributes in the UX. Even if the UX was predominantly positive because the hedonistic gap in the area of the Web sessions was compensated relatively easily by the F2F sessions, this does not mean that BSCT cannot be further improved to increase adherence and long-term abstinence. Hedonism could be a starting point for this. Further research on the following questions could be useful:

Could the hedonistic gap in the Web sessions be not only due to the mode of delivery, but also the concrete content of the Web sessions? Perhaps, it was precisely the interventions that the patients experienced as nonhedonistic, which were the part of the Web sessions. This was neither explicitly considered in the treatment design nor asked for in detail in the interviews. However, this might have been the case because more standard exercises and messages could be offered on the Web more easily. A stronger involvement of patients in the early design stages of the Web sessions may help to prevent the hedonistic gap.

May hedonism play a less prominent role in the health care context than in the other domains? Patients tend to approach a health problem with a pragmatic-neutral expectation, such as "What's important is that it works. As long as it helps, I can also accept that it is unpleasant." Consequently, hedonistic aspects, such as fun, enjoyment, pleasure, and aesthetics may not be expected in the first place, and therefore, may not be missed. Moreover, this may be compensated relatively easily by positive experiences with the counselors. However, if hedonism was less important in health care, it would contradict our conclusion that it should receive more attention.

Could both scientific research and clinical practice use insights from persuasive systems design (Kelders, Kok, Ossebaard, & Van Gemert-Pijnen, 2012; Lehto & Oinas-Kukkonen,

2011), “nudging” (Vlaev, King, Dolan, & Darzi, 2016), and “funology” (Hassenzahl, 2003, 2018) to address the hedonic gap, which may negatively influence smoking cessation patients who are usually a highly motivated target group (Perski, Herd, West, & Brown, 2019)? Persuasive design features, such as primary task support (e.g., tailoring, personalization), dialogue support (e.g., rewards, liking), credibility support (e.g., real-world feel), social support (e.g., normative influence, competition), and hedonic aspects (e.g., fun, enjoyment, pleasure, and aesthetics) may play a role in sustaining patients’ motivation to adhere to the treatment and quit smoking.

How do the apparent character and the consequential appeal and emotions relate to the quitting behavior? On the one hand, apparently a negative appeal (ie, missing hedonic attributes) may lead to consequential combination of negative appeal, emotions, and behavior (i.e., neither adhere nor quit). On the other hand, it is also possible to distinguish between diverse episodic UXs ultimately leading to a cumulative UX (Roto et al., 2011), for example, a motivated patient may start with a positive UX but after failing to quit or relapsing, the patient’s standards and expectations may change during the treatment, which can then lead to a negative appeal and ultimately to a cumulative negative UX. The cumulative UX would then not be the result of a linear process as in the model of Hassenzahl (Figure 1). Rather, in a circular process, consequences (i.e., quitting), apparent character, expectations, and standards would influence each other.

STRENGTHS AND LIMITATIONS

The data and model used in this study provided a rich insight into the UX of a blended treatment for smoking cessation in an ambulant clinical setting. Though this study yielded valuable knowledge for the understanding and improvement of BSCT and the matching of patients and treatment, limitations should be noted when interpreting the findings. First, the sample of patients used in this study was a purposive sample that was intended to represent the heterogeneity of the patients of an outpatient cessation clinic. Hence, it is uncertain, if the rather small sample (n=10) is representative of the population referring to characteristics, such as sex, age, internet skills, or educational level, and if the thematic saturation was reached with this sample size. It should also be considered that patients did not choose BSCT on their own but were randomly assigned to it because they participated in a randomized controlled trial. However, the high degree of consensus in the findings may indicate generalization of our main conclusions. Second, the interviews were conducted retrospectively. Conducting additional interviews at treatment start and during treatment could have offered a more valid insight in the process of patients’ UX construction (e.g., for the standards, expectations, and apparent character). Third, the software that was used for the Web sessions was developed around 2005, which may have led to technical incommodities (e.g., Web software is “Flash”-based and nonresponsive; not mobile device–compatible), which may have negatively impacted the UX. This assumption is based on the fact that patients often stated that they would have liked to do the Web sessions on their mobile device. We assume that a newer mobile device–compatible software with similarly good pragmatic attributes as the previous Flash-software could have also improved the hedonistic attributes and thus have led to more positive consequences. Fourth, the interviews were conducted with the first patients that followed the new blended version of the smoking cessation treatment. At that time, the treatment still had some teething problems, such as being new for the originally F2F counselors. We did not integrate the counselors’ views on the uptake of BSCT, and therefore, we cannot compensate for bias through inadequate treatment fidelity. Fifth, as long-term abstinence is the goal of a smoking cessation treatment, prolonged follow-up analysis of patients’ UX could reveal a different picture. For example, some patients may continue using the Web-based modality and benefit from this at a later stage, resulting in a UX that would be more in favor of the Web-based treatment. Conversely, relapse to smoking at a later stage may lead to a negative adjustment of the UX of the blended treatment. Sixth, we could not elaborate further on which specific parts of the Web sessions were experienced positively or negatively as we did not ask for these in detail in the interviews. Seventh, the study interventions are selected and combined by the researchers and treatment developers without considering the individual patients who ultimately followed the treatment. This resulted in a rather inflexible approach of blending (five Web-based sessions and five F2F sessions in a fixed sequence and with equivalent content) to allow for comparisons with the F2F treatment as usual in the randomized controlled trial (LiveSmokefree study) [8]. This inflexible approach is due to the research design and may limit the potential of blending. In daily practice, the blending of Web-based and F2F intervention may lead to a flexible exchangeability of all intervention components, which would foster a treatment that is highly tailored to the patient’s needs and abilities and could lead to a different UX.

CONCLUSIONS

This study provides insight into the key elements of the UX of a blended treatment for smoking cessation and supports the expectation that in a blended treatment, one mode of delivery may compensate for the weaknesses of the other. However, in this certain setting, this could be mainly achieved in only one way: F2F sessions compensated for the weaknesses of the Web sessions. As a practical conclusion, this may mean that the Web sessions supported by the strength of the F2F sessions, offer an interesting approach for further improving the blended treatment in this specific context. Our theoretical findings reflect the relevance of the aspects of hedonism, such as fun, joy, or happiness in UX (Hassenzahl, 2018), which were not mentioned in relation to the Web sessions and only scarcely mentioned in relation to the F2F sessions. Future research should further investigate the role of hedonistic aspects in the blended treatment and if increased enjoyment of the

blended treatment could increase the treatment adherence and ultimately its effectiveness.

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Authors' Contributions

LS, SA, MP, MK, and MEP identified the study questions and designed the study. LS is principal investigator and prepared the first draft of this manuscript. LS, SA, MP, MK, MEP, and RS edited this manuscript. LS, SA, and MP revised the manuscript. All authors approved the final version of this manuscript for publication.

Conflicts of Interest

None declared.

Abbreviations

BSCT	Blended Smoking Cessation Treatment
eHealth	Electronic health
F2F	Face-to-face
SRP	Outpatient Smoking Cessation Clinic (Dutch: Stoppen met Roken Poli)
UX	User experience

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Adherence - Measurement, Levels, and Predictors

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ABSTRACT

BACKGROUND

Blended face-to-face and Web-based treatment is a promising way to deliver cognitive behavioral therapy. Since adherence has been shown to be a measure for treatment's acceptability and a determinant for treatment's effectiveness, in this study, we explored adherence to a new blended smoking cessation treatment (BSCT).

OBJECTIVE

The objective of our study was to (1) develop an adequate method to measure adherence to BSCT; (2) define an adequate degree of adherence to be used as a threshold for being adherent; (3) estimate adherence to BSCT; and (4) explore the possible predictors of adherence to BSCT.

METHODS

The data of patients (N=75) were analyzed to trace adherence to BSCT delivered at an outpatient smoking cessation clinic. In total, 18 patient activities (eg, using a Web-based smoking diary tool or responding to counselors' messages) were selected to measure adherence; the degree of adherence per patient was compared with quitting success. The minimum degree of adherence of patients who reported abstinence was examined to define a threshold for the detection of adherent patients. The number of adherent patients was calculated for each of the 18 selected activities; the degree of adherence over the course of the treatment was displayed; and the number of patients who were adherent was analyzed. The relationship between adherence and 33 person-, smoking-, and health-related characteristics was examined.

RESULTS

The method for measuring adherence was found to be adequate as adherence to BSCT correlated with self-reported abstinence (P=.03). Patients reporting abstinence adhered to at least 61% of BSCT. Adherence declined over the course of the treatment; the percentage of adherent patients per treatment activity ranged from 82% at the start of the treatment to 11%-19% at the final-third of BSCT; applying a 61% threshold, 18% of the patients were classified as adherent. Marital status and social modeling were the best independent predictors of adherence. Patients having a partner had 11-times higher odds of being adherent (OR [odds ratio]=11.3; CI: 1.33-98.99; P=.03). For social modeling, graded from 0 (=partner and friends are not smoking) to 8 (=both partner and nearly all friends are smoking), each unit increase was associated with 28% lower odds of being adherent (OR=0.72; CI: 0.55-0.94; P=.02).

CONCLUSIONS

The current study is the first to explore adherence to a blended face-to-face and Web-based treatment (BSCT) based on a substantial group of patients. It revealed a rather low adherence rate to BSCT. The method for measuring adherence to BSCT could be considered adequate because the expected dose-response relationship between adherence and quitting could be verified. Furthermore, this study revealed that marital status and social modeling were independent predictors of adherence.

TRIAL REGISTRATION

Netherlands Trial Registry NTR5113; http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=5113 (Archived by WebCite at http://www.webcitation.org/71BAPwER8).

INTRODUCTION

SMOKING CESSATION TREATMENT

As smoking is the leading cause of preventable death, cessation treatment remains pivotal for public health promotion. In past decades, a variety of effective interventions for smoking cessation have become available (Lancaster & Stead, 2017; Stead, Koilpillai, Fanshawe, & Lancaster, 2016), including, more recently, Web-based interventions (Civljak, Stead, Hartmann-Boyce, Sheikh, & Car, 2013; Taylor et al., 2017) and mobile-phone interventions (Whittaker et al., 2009; Whittaker, McRobbie, Bullen, Rodgers, & Gu, 2016). Currently, both traditional and Web-based modes of delivery are being increasingly merged into blended treatment.

BLENDED TREATMENT

Blended treatment is a promising way to deliver behavioral change interventions as it allows combining the strengths of face-to-face treatment (personal attention of a professional, allowing for rich and dynamic synchronous communication) with the unique features of Web-based care (accessibility anytime and anywhere, self-paced asynchronous communication)(Barak, Hen, Boniel-Nissim, & Shapira, 2008; Erbe, Eichert, Riper, & Ebert, 2017; Postel, Witting, & Gemert-Pijnen, 2013; Siemer et al., 2016; van der Vaart et al., 2014; Wentzel, van der Vaart, Bohlmeijer, & van Gemert-Pijnen, 2016). In the recent past, a growing body of research on blended treatment has emerged (Erbe et al., 2017; Kloek, Bossen, de Bakker, Veenhof, & Dekker, 2017) exploring diverse aspects such as individual and group treatments (Schuster, Leitner, Carlbring, & Laireiter, 2017) for a number of health issues, such as depression (Kooistra et al., 2014), anxiety (Bruinsma, Kampman, Exterkate,

& Hendriks, 2016), and addiction (Siemer et al., 2016); comparing modes of delivery, such as mainly Web-based (Harrington et al., 2012; Massoudi et al., 2017), mainly face-to-face (Bruinsma et al., 2016; Mansson, Skagius Ruiz, Gervind, Dahlin, & Andersson, 2013), and 50-50 (Kooistra et al., 2016); orders of modes of delivery, such as integrated (Siemer et al., 2016) and sequential (Harrington et al., 2012); and tools used, such as platforms, emails, short message service text messaging, and apps (Kemmeren et al., 2016; Kleiboer et al., 2016).

ADHERENCE

While blended treatment may decrease dropout rates (Erbe et al., 2017), it may also increase adherence, which is often low in both Web-based and cessation treatments (Donkin et al., 2011). Adherence can be defined as the extent to which a person's behavior—taking medication, following a diet, or executing lifestyle changes—corresponds with recommendations from a health care provider (Sabaté, 2003). In the context of behavioral change treatments (e.g., smoking cessation counseling), issues of adherence are mostly related to premature termination of the treatment and failures to complete between-session tasks and exercises (Bosworth, 2010). Low adherence is both an indicator for limited treatment acceptability and a primary determinant of treatment effectiveness (Alterman, Gariti, Cook, & Cnaan, 1999; Fish et al., 2009; Sabaté, 2003; Westman, Behm, Simel, & Rose, 1997) because it leads to suboptimal exposure of patients to evidence-based components of treatment, which in turn—assuming a dose-response relationship—negatively affects treatment outcome (Sabaté, 2003).

ADHERENCE TO BLENDED TREATMENT

Until now, little has been known about adherence to blended treatment. In a randomized controlled trial (RCT; N=97), comparing the blended treatment of comorbid mental health and substance use problems with face-to-face treatment, participants were found to be equally able to engage, bond, and commit to treatment (Kay-Lambkin, Baker, Lewin, & Carr, 2011). However, in another RCT (N=45), adherence was significantly lower for blended depression treatment than for face-to-face treatment (90.5% vs 95.1%), although both treatments were equally effective (Wright et al., 2005). Based on a small sample (N=9) in another blended depression treatment trial, adherence rates were considered promising (i.e., 5 of 7 patients who started blended treatment completed 90% of it) (Kooistra et al., 2016). This initial evaluation study also revealed that discontinuing blended treatment appeared to be unrelated to the blended nature of the treatment and, unsurprisingly, having internet access and a functional computer at home was indispensable. Finally, a case report on blended treatment for antepartum depression also showed good adherence (Hantsoo, Epperson, Thase, & Kim, 2013).

In the context of smoking cessation, to the best of our knowledge, adherence to blended treatment has not been assessed. For smoking cessation treatment in general, adherence rates widely vary between studies (5%-96%), which can be explained by differences in the interventions used, adjunctive support, and populations studied (Sabaté, 2003). Typically, in a smoking cessation treatment, adherence rapidly declines over the initial weeks of treatment, followed by a more gradual decrease in the later stages, resulting in rather low adherence rates (<40%) (Sabaté, 2003).

PREDICTORS OF ADHERENCE

As adherence is pivotal for treatment effectiveness (Sabaté, 2003), predicting adherence becomes relevant because it may increase treatment efficacy. Adherence, in general, is determined by provider behaviors, health system factors, and personal characteristics (Sabaté, 2003). In particular, the latter have been examined as predictors of adherence to traditional interventions (Hotz et al., 2003). However, similar studies on adherence to blended treatment appear to be lacking. Within the context of smoking cessation treatment—including both face-to-face and Web-based treatments—several person-, smoking-, and health-related predictors of adherence have been examined. The likelihood of being adherent increases with a higher age (Ben Taleb, Ward, Asfar, Bahelah, & Maziak, 2015; Hays, Leischow, Lawrence, & Lee, 2010), male gender (Ben Taleb et al., 2015), higher internet skills (Gerhards et al., 2011; Mathew, Morrow, Frierson, & Bain, 2011), negative attitude toward smoking and higher motivation to quit at baseline (Asfar, Al Ali, Rastam, Maziak, & Ward, 2014; Heffner, Lewis, & Winhusen, 2013), higher self-efficacy at baseline (Heffner et al., 2013), early success in quitting after the start of the treatment (Alterman et al., 1999; Busnello et al., 2001; Hays et al., 2010), and lower nicotine dependency at baseline and fewer withdrawal symptoms after quitting (Asfar et al., 2014; Ben Taleb et al., 2015). The question arises whether these predictors apply to blended treatment as well.

MEASUREMENT OF ADHERENCE

To examine the predictors of adherence, valid measurement of adherence becomes a prerequisite. Taking into account both the novelty and diversity of blended treatments, one can understand that established measures for adherence to blended treatment in particular are still lacking. Therefore, for the purpose of this study, a customized measure was constructed based on a combination of parameters used for face-to-face and Web-based interventions. In face-to-face treatment, adherence is often operationalized as completion of tasks assigned during the treatment or the number of completed or attended treatment sessions (Lopez-Torrecillas, Rueda, Lopez-Quirantes, Santiago, & Tapioles, 2014). In Web-based treatment, the measures of adherence often comprise log-ins to programs, module completion, time spent online, (self-reported) completion of predefined activities such as use of an Web-based tool, posts made, pages viewed, replies to emails, forum visits, or

print requests made (Donkin et al., 2011). Aiming to increase precision and accuracy, the adherence measure developed for this study was primarily based on objective or direct adherence indicators, such as whether or not a patient attended a face-to-face session, responded to a counselor's message, or used a certain Web-based treatment tool (e.g., "goal setting" or "think differently"). Using observable and digitally traceable patient activities, limitations in terms of reliability and validity of self-report data (Prince et al., 2008) can be largely avoided.

THRESHOLDS DEFINING "ADEQUATE" AND "INADEQUATE" ADHERENCE

Finally, in addition to measuring adherence as a continuous variable, applying a categorical measure based on a threshold for "adequate" and "inadequate" adherence may be useful for clinical purposes (Hays et al., 2010). However, justifications for the operationalizations of thresholds are a common issue; a recent review (Sieverink, Kelders, & van Gemert-Pijnen, 2017) on adherence to eHealth revealed that 28 of 62 studies described thresholds, but only 6 reported a justification for the threshold. In line with Carolan (Carolan, Harris, Greenwood, & Cavanagh, 2016), in this study, we have defined the threshold in relation to the treatment outcome (ie, quitting smoking). To the best of our knowledge, neither for blended smoking cessation treatment (BSCT), in particular, nor for blended treatment, in general, have the thresholds for adherence been explored until now. In the context of smoking cessation, intervention thresholds for classifying participants as adherent or nonadherent range from 75% to 100% use of intervention components offered (Sabaté, 2003).

OBJECTIVES

In view of all that has been mentioned so far, the objectives of this exploratory study were as follows:

1. To develop a method to measure adherence to a BSCT by selecting traceable activities of the patients and to determine whether this method is adequate by comparing the degree of adherence with the quitting success (ie, verifying the expected dose-response relationship between adherence and quitting).
2. To define an adequate degree of adherence to be used as a threshold to detect adherent patients by examining the minimum degree of adherence of the patients who reported abstinence.
3. To estimate adherence to BSCT in three ways: by calculating the number of adherent patients for certain treatment activities; by displaying how the degree of adherence changes over the course of the treatment; and by reporting the proportion of adherent patients according to the threshold for adherence.
4. To explore the possible predictors of adherence to BSCT by examining the relationship between being adherent or nonadherent and 33 person-, smoking-, and health-related characteristics assessed at baseline.

METHODS

STUDY PARTICIPANTS

In this study, we used a subset of an RCT on the effectiveness of BSCT versus face-to-face treatment as usual (Siemer et al., 2016). Patients were referred to the outpatient smoking cessation clinic at the Medical Spectrum Twente hospital (Enschede or The Netherlands) by the treating physicians of the hospital or by the patients' general practitioners. Inclusion criteria included (1) being at least 18 years old, (2) currently smoking (at least one cigarette a day), (3) having access to email and internet, (4) being able to read and write Dutch. For the adherence analysis, we used the RCT data of the first 75 patients of the BSCT who attended an initial treatment session from May 2015 to December 2016. In line with the Dutch Medical Research Ethics Committee (MREC) guidelines, the study was approved by the accredited MREC Twente (P14-37/NL50944.044.14). Before initiation, the study was registered in the Dutch Trial Registration (NTR5113). All patients had to sign an informed consent form before they were randomized.

BLENDED SMOKING CESSATION TREATMENT

The BSCT examined in this study is a combination of face-to-face treatment and Web-based sessions blended into one integrated smoking cessation treatment, which is delivered in routine care settings. BSCT consists of 5 face-to-face sessions at the outpatient clinic and 5 Web-based sessions delivered via the Web-based treatment platform. Table 6 shows the order, timing, main features, and mode of delivery of the sessions.

TABLE 6. Order, timing, main features, and mode of delivery of blended smoking cessation treatment.

Session	Week	Main features	Mode of delivery
1	1	Goal setting, Prompt smoking diary, Measure CO[a]	face-to-face
2	3	Measures for self-control	web-based
3	5	Dealing with withdrawal	face-to-face
4	7	Breaking habits	web-based
5	9	Dealing with triggers	face-to-face
6	11	Food for thought	web-based
7	14	Think differently, Measure CO[a]	face-to-face
8	18	Do differently	web-based
9	22	Action plan, Measure CO[a]	face-to-face
10	26	Closure	web-based

[a]CO: carbon monoxide.

The following are the characteristic features of BSCT:

High-intensity treatment: BSCT comprises 10 sessions (20 minutes each, except the first one, which is of 50 minutes); it covers the majority of evidence-based behavior change techniques

(West, Walia, Hyder, Shahab, & Michie, 2010). It is derived from the Dutch Guideline Tobacco Addiction (Partnership Stop met Roken, 2017), fulfilling the requirements of the Dutch care module for smoking cessation (Partnership Stop met Roken, 2009); the counselors are registered in the Dutch quality register of qualified smoking cessation counselors.

Supports three quitting strategies: At the start, patients choose to (1) stop at once, (2) change gradually by increasing the number of daily activities that are performed smoke-free, or (3) decrease smoking at regular intervals (scheduled smoking reduction, eg, 100%->75%, 75%->50%). The chosen quitting strategy does not influence the course of the treatment in general, that is, the order, pace, duration, and intensity are the same for all strategies.

A 50-50 balance between face-to-face and Web-based treatments: The focus of the treatment is neither on face-to-face nor on Web-based treatment; in addition, the treatment is constantly alternating and there is interactive use of face-to-face and Web-based treatments.

A detailed description of the treatment can be found in the protocol article of the RCT (Siemer et al., 2016).

DATA COLLECTION

Patients' Characteristics and Smoking Status

As part of the RCT, 33 person-, smoking-, and health-related characteristics were assessed with the intake measurement using a Web-based questionnaire. A detailed description of these characteristics is available in the protocol article of the RCT (Siemer et al., 2016). In addition, both the 3-month and 6-month follow-up measurements of the trial were used to examine the self-reported smoking status.

MEASURING ADHERENCE TO BLENDED SMOKING CESSATION TREATMENT

Two data sources were screened to determine which treatment activities of the patients could be traced after the first treatment session:

1. The patients' record from the Web-based treatment platform. These records provided, on the one hand, a section where patients and counselors communicated via messages and, on the other hand, a section with therapeutic Web-based tools that were used by the patient. Both sections interact with each other. Here is a typical example of this interaction: The counselor sends a message with instructions to use a therapeutic Web-based tool, such as "goal setting." With this message, the counselor also unblocks the goal setting Web-based tool and sets a date for executing this task. After receiving this message, the patient uses the unblocked Web-based tool to elaborate goals. What the patient fills in can then be reviewed by the counselor, who also has access to the tool. The counselor then usually responds to what the patient filled in via a message and leads into the following face-to-face session.
2. Patients' records from the outpatient cessation clinic, which were maintained by the counselors. These records provided additional information about patients' activities, such as adhering to a stop-date or measurement of CO.

After comparing the treatment manual with the data available in the two data sources, 18 activities of patients were selected to score adherence after the first treatment session. The selection of activities was based on the following three considerations:

1. The activity had to refer directly to a relevant evidence-based behavior change technique (West et al., 2010) (e.g., goal setting, action plan) that represented the main feature of the sessions, so that adherence to each of the 10 sessions of the treatment was separately measurable.
2. The activities had to trace both face-to-face and Web-based behaviors of patients (e.g., attending face-to-face treatment sessions as in "Think differently [face-to-face]" or completion of predefined Web-based tasks as in "Think differently [Web]"), so that adherence to the constant interaction between face-to-face and Web-based treatments—and by this, the blended nature of BSCT—was covered.
3. The data used had to be objective (e.g., receiving a message, unblocking a Web-based tool, filling in a minimal number of data in a Web-based tool) to avoid the limitations of self-reported data (Prince et al., 2008).

The majority of the selected activities reflected the course of the blended treatment, starting with "Goal setting (face-to-face)" at the end of session 1 and finalizing with "Action plan (Web)" in session 10. Three activities were not session dependent as they had to be executed several times ("Measurement of CO [face-to-face]") or across several sessions ("smoking diary [days; Web]"; "smoking diary [moments; Web]"). A detailed description of these activities showing how each activity was operationalized to indicate adherence or nonadherence is provided in Table 7.

Based on data sources, for each patient, adherence to each of the 18 activities was assessed and graded adherent or nonadherent by trained research assistants. Finally, for each patient, an adherence score from 0 (adherent to no activity after the first treatment session) to 18 (adherent to all activities) as well as subscores for Web-based versus face-to-face and session-dependent versus session-independent activities were available.

TABLE 7. Activities, operationalization and patients' adherence to BSCT (n=75)

Session	Activity (mode of delivery[a])	Operationalization	Adherent patients (%)
Session-dependent activities			
1	Goal setting (f2f)[a]	The patient was introduced to "goal setting" and received a message with the prompt to use the online goal setting tool.	62 (82%)
1	Goal setting (web)[a]	The patient used the online goal setting tool.	44 (58%)
2	Measures for self-control (f2f)	The patient was introduced to "measure for self-control" and received a message with information about measures for self-control.	39 (52%)
2	Measures for self-control (web)	The patient reacted to the measure for self-control message. (Note: reaction was not obligatory: patients may read only without responding)	27 (36%)
3	Dealing with withdrawal (f2f)	The patient was introduced to "dealing with withdrawal" and received a message with information about dealing with withdrawal.	31 (41%)
3	Dealing with withdrawal (web)	The patient reacted to the dealing with withdrawal message. (Note: reaction was not obligatory: patients may read only without responding)	20 (26%)
5	Dealing with tempters (web)	The patient received a message with information about dealing with tempters.	22 (29%)
6	Food for thought (f2f)	The patient was introduced to "food for thought" and received a message with information about food for thought.	17 (23%)
6	Food for thought (web)	The patient reacted to the food for thought message (Note: reaction was not obligatory: patients may read only without responding)	8 (11%)
7	Think differently (f2f)	The patient was introduced to "think differently" and received a message with the prompt to use the online think differently tool.	14 (19%)
7	Think differently (web)	The patient used the online think differently tool.	14 (19%)
8	Do differently (f2f)	The patient was introduced to "do differently" and received a message with the prompt to use the online do differently tool.	12 (16%)
8	Do differently (web)	The patient used the online Do differently tool.	14 (19%)
9	Action plan (f2f)	The patient was introduced to "action plan" and the patient received a message with the prompt to use the online action plan tool.	13 (17%)
10	Action plan (web)	The patient used the online action plan tool.	13 (17%)
Session-independent activities			
Measurement of CO (f2f)		The counsellor reported at least two CO measurements.	34 (45%)
Smoking diary (days) (web)		The patient used the online smoking diary tool registering cigarettes smoked for at least three days.	26 (35%)
Smoking diary (moments) (web)		The patient used the online smoking diary tool describing at least three moments with an urge to smoke.	31 (41%)

[a]mode of delivery: f2f = face-to-face treatment, web = web-based treatment

PATIENTS' CHARACTERISTICS

Patients' person-, smoking-, and health-related characteristics were reported as means with SDs for normally distributed continuous variables and as medians with interquartile ranges (IQRs) for not-normally distributed continuous variables. Categorical variables were reported as numbers with corresponding percentages.

Dose-Response Relationship Between Adherence and Quitting

To explore the association between the degree of adherence and quitting success, the median number of adherence activities was compared between quitters (based on self-reported smoking status) and smokers at 3 and 6 months after the start of the treatment and tested using Mann-Whitney-U test.

Threshold to Detect Adherent Patients

To define a threshold for an adequate degree of adherence, the minimum number of adherence activities of quitters (6 months after the start of the treatment) was examined and displayed as number (%) of activities for BSCT overall and separately for both face-to-face and Web-related activities.

ADHERENCE TO BLENDED SMOKING CESSATION TREATMENT

Adherence per Activity

To examine the degree of adherence to each of the BSCT activities, the number (%) of patients fulfilling each activity was examined and displayed separately.

Adherence Over the Course of the Treatment

To show changes in adherence over the course of the treatment, the number of patients who were adherent to session-dependent activities was displayed in a bar chart.

Adherence Based on the Threshold

The number (%) of patients who were adherent and nonadherent based on the determined threshold to detect adherent patients was cross-tabulated for both the face-to-face and Web-based modes. The number of adherent patients was compared between face-to-face and Web-based treatments and tested using Pearson chi-square test.

PREDICTORS OF ADHERENCE

To identify the predictors of adherence within the 33 person-, smoking-, and health-related patient characteristics, t tests or Mann-Whitney-U tests were performed as appropriate for continuous variables; Pearson chi-square or Fisher's exact test were performed for categorical variables. Variables with a significance P<.15 were considered as the candidates for multivariate logistic regression analyses and were entered after checking for multicollinearity. Forward stepwise logistic regression analyses were performed. Variables were entered step for step and were eliminated when the model fit was not significantly increased by adding the variable (based on −2 log likelihood). In case of multicollinearity, the variable with the best model fit was selected for logistic regression analyses.

STATISTICAL ANALYSIS

All analyses were performed using SPSS version 24.

RESULTS

PATIENTS' CHARACTERISTICS

Patients' person-, smoking-, and health-related characteristics are shown in Table 8.

TABLE 8. Predictors of adherence/non-adherence to BSCT

Predictor		Adherent (n=14)	non-adherent (n=61)	*P* value
Person-related				
Sex				
	Female (%)	3 (21)	31 (51)	.05[a]
	Male (%)	11 (79)	30 (49)	
Age				
	Years, median (IQR)	55 (38-61)	45 (33-58)	.17
Marital status				
	With partner (%)	13 (93)	38 (62)	.03[a]
	Alone (%)	1 (7)	23 (38)	
Housing situation				
	With children (%)	6 (43)	26 (43)	.99
	Without children (%)	8 (57)	35 (58)	
Education				
	VET or higher (%)	7 (50)	36 (59)	.54
	Lower than VET (%)	7 (50)	25 (41)	
Main income				
	Wage or own company (%)	11 (79)	30 (49)	.05[a]
	Income support (%)	3 (21)	31 (51)	
Main day activity				
	Paid work (%)	10 (71)	31 (51)	.16
	Other (%)	4 (29)	30 (49)	
Internet skills				
	Median (IQR)	36.5 (35.8-40.5)	38.0 (34.0-41.0)	.98
Smoking-related				
Reason to start treatment				
	Intrinsic (%)	11 (79)	40 (66)	.53
	Extrinsic (%)	3 (21)	21 (34)	
Nicotine dependency (Fagerstroem)				
	Median (IQR)	5 (4-7)	6 (4-7)	.53
Negative attitude towards quitting				
	Median (IQR)	-5.0 (-6.0 - -3.5)	-6 (-3.5 - -9.0)	.33
Positive attitude towards quitting				
	Median (IQR)	9.5 (8.0-10.3)	10 (8.0-11.5)	.69
Self-efficacy				
	Median (IQR)	0 (-3.3-5.3)	-1 (-5.0-3.0)	.34
Readiness to quit				
	Median (IQR)	2.0 (1.0-3.0)	2.0 (1.0-3.0)	.88
Earlier quit attempts				
	Yes (%)	11 (79)	51 (84)	.70
	No (%)	3 (21)	10 (16)	

TABLE 8 continued.

Predictor		Adherent (n=14)	non-adherent (n=61)	*P* value
Social support				
	Median (IQR)	4.0 (3.0-4.3)	4.0 (3.0-4.0)	.57
Social modelling				
	Median (IQR)	2.0 (0.0-4.3)	4.0 (1.0-6.0)	.05[a]
Use of alcohol				
	Median (IQR)	3 (1-4)	2 (1-3)	.08[a]
Use of (recreational) drugs				
	Yes (%)	0 (0)	8 (13)	.34
	No (%)	14 (100)	53 (87)	
Health-related				
Use of medication in general				
	Yes (%)	8 (57)	36 (59)	.90
	No (%)	6 (43)	25 (41)	
Use of medication for addiction treatment				
	Yes (%)	0 (0)	0 (0)	[b]
	No (%)	14 (100)	61 (100)	
Use of medication for psychiatric treatment				
	Yes (%)	3 (21)	9 (15)	.69
	No (%)	11 (79)	52 (85)	
Use of medication for physical treatment				
	Yes (%)	4 (29)	29 (48)	.20
	No (%)	10 (71)	32 (52)	
Use of other medication				
	Yes (%)	4 (29)	6 (10)	.08[a]
	No (%)	10 (71)	55 (90)	
Health complaints (MAP HSS)				
	Median (IQR)	9.5 (6.8-13.0)	11.0 (7.0-19.0)	.08[a]
Smoking related complaints				
	Median (IQR)	17.0 (9.5-22.3)	21.0 (15.5-27.5)	.13[a]
Health and smoking related complaints				
	Median (IQR)	28.5 (13.8-35.3)	37.0 (23.5-47.5)	.08[a]
Depression				
	Median (IQR)	4.0 (1.5-13.0)	4.0 (0.0-10.0)	.75
Anxiety				
	Median (IQR)	3.0 (2.0-6.0)	4.0 (2.0-9.0)	.52
Stress				
	Median (IQR)	5.0 (1.5-13.5)	8.0 (4.0-15.0)	.34
DASS				
	Median (IQR)	14.0 (4.0-32.5)	20.0 (9.0-31.0)	.49
Euroqol-5D				
	Median (IQR)	0.80 (0.73-1.0)	0.80 (0.69-1.0)	.27
Euroqol-5D VAS				
	Median (IQR)	70 (63-80)	70 (59-80)	.86

[a] Variable entered in the multivariate logistic regression model based on *P* value ≤ 0.15
[b] no *P* value computed because variable is a constant
IQR, inter quartile range; SD, standard deviation;
VET, vocational education and training; Internet skills (range 10-60; higher number indicates better skills); Fagerstroem (higher numbers indicate higher nicotine dependency); Negative attitude towards quitting (lower numbers indicate a

more negative attitude towards quitting smoking); Positive attitude towards quitting (higher numbers indicate a more positive attitude towards quitting smoking); Self-efficacy (higher numbers indicate higher self-efficacy related to smoking cessation); Readiness to quit (higher numbers indicate higher readiness to quit); Social support (higher numbers indicate more social support in smoking cessation); Social modelling (higher numbers indicate more smokers in the social environment); Use of alcohol (higher numbers indicate higher alcohol consumption); Health complaints (MAP HSS), Maudsley Addiction Profile Health Symptoms Scale (higher numbers indicate poorer health status), Smoking related complaints (higher numbers indicate more smoking related complaints); Health and smoking related complaints (higher numbers indicate poorer health status and more smoking related complaints); Depression/Anxiety/Stress (higher number indicate a higher level of depression/anxiety/stress); DASS, sum score of Depression/Anxiety/Stress (higher numbers indicate a more negative emotional status); Euroqol-5D, societal-based quantification of the patients' health status (higher numbers indicate better health status); Euroqol-5D VAS, visual analogue scale for quality of life (higher numbers indicate better state of health)

DOSE-RESPONSE RELATIONSHIP BETWEEN ADHERENCE AND QUITTING

A subsample of patients' self-reported smoking status at 3 months (n=25) and 6 months (n=17) after the start of the treatment was available to explore the relationship between adherence and quitting. As can be seen by the numbers of activities for adherence tabulated in Table 9, there is a dose-response relationship between adherence to BSCT and self-reported smoking status at 3 and 6 months after the start of the treatment. The median number of activities for adherence is significantly higher among quitters at 6 months after the start of the treatment (P=.03).

TABLE 9. Adherence to BSCT and self-reported smoking status at three and six months after The start of The treatment

Time point	Median number of adherence activities (IQR[a])		
	Quitter	Smoker	*P* value
3 months (n=25)	14.5 (IQR 9.5-15.8)	9.0 (IQR 6.0-14.0)	.08
6 months (n=17)	15.0 (IQR 11.8-16.0)	9.0 (IQR 6.5-14.5)	.03

[a]IQR: interquartile range

THRESHOLD TO DETECT ADHERENT PATIENTS

Patients with self-reported abstinence at 6 months after the start of the treatment (n=17) were adherent to at least 61% (11/18) activities of BSCT. Because BSCT is built on a 50%-50% relation for both modes of delivery, a 61% threshold was applied to both modes of delivery to detect adherent patients (ie, patients were defined as adherent if 5 of the 8 face-to-face activities as well as 6 of the 10 Web-based activities were fulfilled).

ADHERENCE TO BLENDED SMOKING CESSATION TREATMENT

Adherence per Activity

Table 7 shows the number (%) of adherent patients for each activity. Of all, 17.3% (13/75) patients were adherent to none of the activities, which indicates that these patients did not

fully complete the first face-to-face session that closes with the patient being introduced to "goal setting" and receiving a message with the prompt to use the Web-based goal setting tool. None of the patients were adherent to all activities.

Adherence per Activity Over the Course of Treatment

To show the change in adherence over the course of the treatment, the number of adherent patients per session-dependent activity (excluding the 3 session-independent activities) is displayed in a bar chart (Figure 2). The number of adherent patients was highest at the start of the treatment (62/75, 82%, patients adherent to "Goal setting [face-to-face]"). Adherence then decreased to 11% (8/75) for the activity "Food for thought (Web)," which is in the 6thtreatment session (Table 7), staying at a low level for the rest of the treatment (varying between 12/75, 16%, and 14/75, 19%).

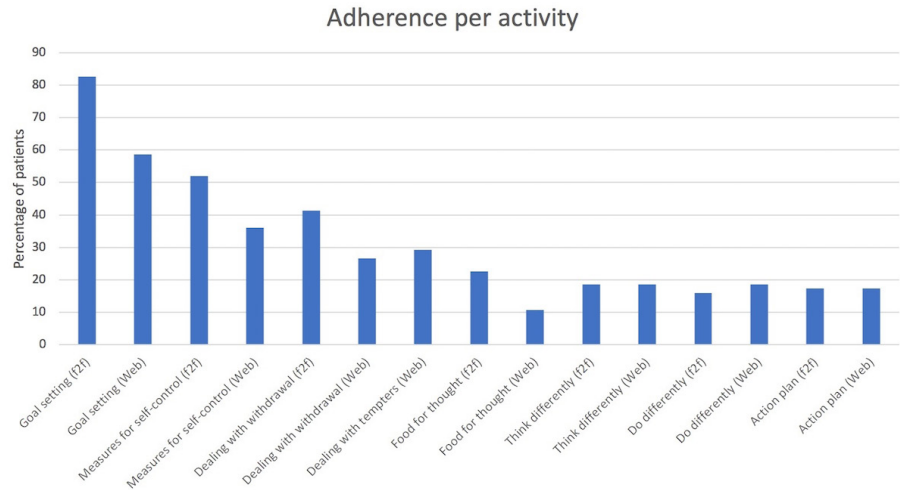

FIGURE 2. Adherence over the course of the treatment. f2f: face-to-face

ADHERENCE BASED ON THE THRESHOLD

Based on the 61% threshold for both modes of delivery, 18% (14/75) patients were adherent to both modes of delivery and, therefore, to BSCT as a whole (Table 10). Of all, 25% (19/75) patients were adherent to the face-to-face treatment compared with 23% (17/75) adherent to the Web-based treatment (P=.70); 70% (53/75) patients were nonadherent to both modes of delivery. Furthermore, 5% (3/75) patients were adherent to the Web-based mode but not to the face-to-face mode, while 7% (5/75) patients were adherent to the face-to-face mode but not to the Web-based mode.

TABLE 10. Adherence to blended smoking cessation treatment based on the 61% threshold (N=75). Percentages are based on the overall N value.

Face-to-face	Web-based		
	Adherent n (%)	Nonadherent n (%)	Total n (%)
Adherent	14 (18)	5 (7)	19 (25)
Nonadherent	3 (5)	53 (70)	56 (75)
Total	17 (23)	58 (77)	75 (100)

PREDICTORS OF ADHERENCE

The 33 person-, smoking-, and health-related characteristics of the 75 patients, stratified by the 61% adherence or nonadherence threshold, are shown in Table 8.

The following predictors were univariately associated with adherence (P<.15): sex (male = more adherent); marital status (with partner = more adherent); main income (wage or own company = more adherent); social modeling (less smokers in the social environment = more adherent) and use of alcohol (higher alcohol consumption = more adherent); use of other medication (user = more adherent); health-related complaints (as per Maudsley Addiction Profile Health Symptoms Scale [MAP HSS]), smoking-related complaints, and health- and smoking-related complaints (less complaints = more adherent). Due to multicollinearity between health-related complaints (MAP HSS), smoking-related complaints, and health- and smoking-related complaints, only the variable with the best model fit could be included in multivariate regression analysis, which was health- and smoking-related complaints.

Multivariate regression analyses revealed that marital status and social modeling—accounting for 25% of the variance (Nagelkerke R Square)—were independent predictors of whether patients were adherent to BSCT. Patients having a partner had 11 times higher odds of being adherent, although the extremely wide CI indicates considerable uncertainty for this odds ratio (OR=11.3; CI: 1.33-98.99; P=.03). For social modeling, graded from 0 (=partner and friends are not smoking) to 8 (=both partner and nearly all friends are smoking), each unit increase was associated with 28% lower odds of being adherent (OR=0.72; CI: 0.55-0.94; P=.02).

DISCUSSION

PRINCIPAL FINDINGS

This study is the first to explore adherence to a blended face-to-face and Web-based smoking cessation treatment (BSCT). Based on a substantial group of participants (N=75), the study revealed a rather low adherence rate to BSCT among this sample of outpatients in a regional hospital in the Netherlands. Applying a 61% threshold for adherence to both face-to-face and Web-based modes of delivery, only 18% (14/75) of the participants were classified as adherent. A dose-response relationship was found between the level of adherence and the likelihood of quitting smoking, corroborating the adequacy of the adherence measure developed for this purpose. Furthermore, several baseline characteristics, in particular marital status and social modeling of nonsmoking, were found to be predictive of adherence to BSCT.

So far, the established measures for adherence to blended treatment are still lacking. Therefore, the first aim of this study was to develop an adequate method for measuring adherence to BSCT and to determine whether this method is adequate. Using data from the hospital's patient records and data logged by patients and counselors on the Web-based treatment platform, a composite score of adherence to 18 distinct treatment activities from both the modes of delivery was calculated. By relying on observed behavior, an objective approach was applied, thus, avoiding bias due to self-report (Prince et al., 2008). Adequacy of the adherence measure was confirmed by the observed dose-response relationship between adherence and likelihood of quitting, which is consistent with smoking cessation literature (Alterman et al., 1999; Fish et al., 2009; Sabaté, 2003; Westman et al., 1997).

A justified threshold for "adequate" and "inadequate" adherence may be useful for clinical purposes (Hotz et al., 2003). Hence, the second aim of the study was to define an adequate level of adherence to be used as a threshold to detect patients adherent to BSCT. We used a 61% threshold, which is derived from the minimum level of adherence of the patients reporting abstinence. Although this 61% threshold is considerably lower than the commonly applied thresholds of >80% in the previous studies (Hays et al., 2010; Kelders, Kok, Ossebaard, & Van Gemert-Pijnen, 2012), it seems realistic if the design of BSCT is taken into consideration. As BSCT is designed as a 10-session, high-intensity treatment, its completion might pose a challenge to the patients of the outpatient clinic. Furthermore, BSCT fosters quitting around month 3 of the treatment while focusing on stabilizing abstinence in the remaining 3 months. Although patients are informed that relapse prevention is pivotal in the later parts of treatment, there seems to be a tipping point at around 60% of the treatment course at which some of the patients who have been successful until then, decide to abandon treatment, thinking themselves "over the hump." This may also be explained by the bidirectional causality between quitting and adherence: early quitting success predicts adherence (Hays et al., 2010), while, in turn, adherence predicts (long-term) abstinence (Alterman et al., 1999; Fish et al., 2009; Sabaté, 2003; Westman et al., 1997).

Because, until now, little has been known about adherence to blended treatment, the third aim of the study was to estimate adherence to BSCT. Not surprisingly, we found a notable

decrease in adherence over the course of the treatment. Only a small proportion of patients (12/75, 16%, to 14/75, 19%) was adherent to the last 4 of the 10 BSCT sessions. This is in line with the <40% adherence rates for the later stages of smoking cessation treatment in general (Sabaté, 2003).

Based on the 61% threshold derived from self-reported abstinence, we found that only 18% (14/75) of the patients were adherent to BSCT. This adherence rate seems to be notably lower than the adherence rates reported in smoking cessation literature, which—while applying even higher thresholds—range from, for example, 50% for Web-based treatment (Kelders et al., 2012) to 70% for face-to-face smoking cessation treatment (Ben Taleb et al., 2015). Explanations for the low adherence may be negative user experience (e.g., due to too demanding or time-consuming features) or lack of persuasive elements (Lehto & Oinas-Kukkonen, 2011) in the Web-based treatment.

We also found no significant difference in adherence to Web-based and face-to-face modalities. This is in line with earlier findings, showing that discontinuing the blended treatment is unrelated to the blended nature of the treatment (Kooistra et al., 2016).

Since predicting adherence may increase treatment efficacy, the fourth aim of the study was to find the predictors of adherence to BSCT. We found being adherent to be significantly (P ≤.05) related to male gender, having a partner, wage or own company as the source of main income, and having a low number of smokers in the social environment. Except for gender (Ben Taleb et al., 2015)], we could not confirm predictors earlier reported in the literature, such as age (Ben Taleb et al., 2015; Hays et al., 2010), internet skills (Gerhards et al., 2011; Mathew et al., 2011), attitude toward smoking and motivation to quit (Asfar et al., 2014; Heffner et al., 2013), self-efficacy (Heffner et al., 2013), and nicotine dependency and withdrawal symptoms (Asfar et al., 2014; Ben Taleb et al., 2015). Furthermore, we found potential predictors of adherence to BSCT (P ≥.05-.15) not earlier reported in the context of smoking cessation treatment, namely use of alcohol, use of other medication, and health- and/or smoking-related complaints. Two predictors—having a partner and having a low number of smokers in the social environment—were found to be unique, independent predictors in the multivariate predictor model. Having a partner gave higher odds of being adherent than living alone. Although not earlier reported in the context of smoking cessation, this seems to be consistent with a meta-analysis about marital status and adherence to medical treatment in general, which found 1.27 (CI: 1.12-1.43) times higher odds of adherence in married than in unmarried patients (DiMatteo, 2004). The most common explanation for this effect of marital status is the social support that a partner may provide to the patient. However, within this study, we did not find a predictive effect of social support, which included the partner as an important other. It should be noted, however, that the measure for social support was specified for smoking cessation and not for adherence. Future research is needed to clarify these inconsistencies. The remarkably high OR of 11 for marital status should be interpreted cautiously because the CI for this ratio was very wide, probably due to limited statistical power in our data. For social modeling, graded from 0 (=partner and friends are not smoking) to 8 (=both partner and nearly all friends are smoking), each unit increase gave 28% lower odds of being adherent. Although not previously reported as a predictor of adherence, social modeling is well known as one of the main determinants of relapse (Cummings, Jaen, & Giovino, 1985; Marlatt & Gordon, 1978; Shiffman, 1982). Apparently, patients with more smokers in their environments have a higher probability to relapse; consequently, they drop out of treatment, resulting in lower adherence. This would also be in line with the bidirectional causality between quitting and adherence mentioned above. Looking at social modeling as a relevant predictor of adherence to BSCT, as a clinical implication, the treatment could offer more normative influence (e.g., showing videos of peers praising quit attempts of others to patients who report high social modeling of smoking in their environment).

LIMITATIONS

A major limitation of this study is that the results found for BSCT have not been compared with either a face-to-face only or a Web-based only treatment. Therefore, it remains undecided whether the results are specific for the blended nature of the treatment or rather for smoking cessation treatment in general.

In addition, the statistical power in this study—especially for predictor analysis—is rather low. This implies, in particular, that false-negative results may have occurred for predictors with small to medium observed effect sizes. As the purpose of this study is primarily exploratory, the risk of false-negative findings was reduced by also considering marginally significant effects as “potential” predictors. However, caution should be taken here, and replication of these findings in future studies is needed.

Furthermore, the adequacy of the adherence measure can be questioned on three aspects. First, 3 of the 10 Web-based activities, “Measure for self-control,” “Dealing with withdrawal,” and “Food for thought,” involved written messages sent by counselors prompting a response by, for example, asking a question at the end of the message. Only when a patient responded and left a traceable action, the activity was scored as completed. Yet, patients may still have read the received messages without explicitly responding to the counselor. This may have led to an underestimation of adherence because the patient may have been exposed to some components without notable traces. Second, the data from the hospital’s patient records and the Web-based treatment platform partly depend on activities of the counselors because they maintain these patients’ records and also act on the Web-based

treatment platform (eg, sending messages to patients, unblocking treatment tools). One can argue, therefore, that adherence measurement is affected by treatment fidelity of counselors. Fidelity of counselors was not evaluated—a common omission in adherence studies (Moncher & Prinz, 1991). Given that, in this particular case, BSCT was new to the counselors, and their potential unfamiliarity with BSCT may have led to not following the treatment protocol strictly. This may also be increased by therapist drift (Waller, 2009), a common phenomenon in face-to-face cognitive behavioral therapy, which involves a shift from "doing therapies" to "talking therapies." Third, although striving for objective measures, whether an activity was fulfilled by a patient was doubtful in some cases; for example, the use of the Web-based goal setting tool was questionable if only one word to set a goal (e.g., "health") was sufficient. These cases had to be discussed in the research team, which adds a subjective factor to the measurement. However, this was only the case for a very small number of participants, mainly in the starting phase of data collection.

Finally, the comparability of the observed adherence rates and thresholds across studies is limited due to variety in treatment demands and operationalizations of adherence (Hotz et al., 2003).

IMPLICATION FOR FUTURE WORK

To assess whether the results found in this study are specific for the blended nature of BSCT, the results should be compared with either face-to-face only or Web-based only treatment. Furthermore, future adherence studies should preferably include a measure of fidelity as well, enabling analyses that control for provider-mediated effects on adherence. In addition, from a clinical perspective, the question arises as to how the low adherence rate to BSCT can be increased by, on the one hand, targeting patients to predictive characteristics at baseline or, on the other hand, redesigning BSCT to better accommodate current population characteristics and needs.

Abbreviations

BSCT	Blended smoking cessation treatment
CO	Carbon monoxide
f2f	Face-to-face
IQR	Interquartile range
MREC	Medical Research Ethics Committee
OR	Odds ratio
RCT	Randomized controlled trial

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Authors' Contributions

LS, MEP, MGJBK, MGP, and AP identified the study questions and designed the study and its measuring instruments. LS is the principal investigator and wrote the first draft of this manuscript. LS, MEP, MGJBK, MGP, AP, RS, and SBA edited this manuscript. LS, MEP, AP, and RS revised the manuscript. All authors approved the final version of this manuscript for publication.

Conflicts of Interest

None declared.

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Adherence - Blended vs. Face-To-Face Treatment

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ABSTRACT

BACKGROUND

Blended face-to-face and web-based treatment is a promising way to deliver smoking cessation treatment. Since adherence has been shown to be an indicator of treatment acceptability and a determinant for effectiveness, we explored and compared adherence and predictors of adherence to blended and face-to-face alone smoking cessation treatments with similar content and intensity.

OBJECTIVE

The objectives of this study were (1) to compare adherence to a blended smoking cessation treatment with adherence to a face-to-face treatment; (2) to compare adherence within the blended treatment to its face-to-face mode and web mode; and (3) to determine baseline predictors of adherence to both treatments as well as (4) the predictors to both modes of the blended treatment.

METHODS

We calculated the total duration of treatment exposure for patients (N=292) of a Dutch outpatient smoking cessation clinic who were randomly assigned either to the blended smoking cessation treatment (n=130) or to a face-to-face treatment with identical components (n=162). For both treatments (blended and face-to-face) and for the two modes of delivery within the blended treatment (face-to-face vs web mode), adherence levels (ie, treatment time) were compared and the predictors of adherence were identified within 33 demographic, smoking-related, and health-related patient characteristics.

RESULTS

We found no significant difference in adherence between the blended and the face-to-face treatments. Participants in the blended treatment group spent an average of 246 minutes in treatment (median 106.7% of intended treatment time, IQR 150%-355%) and participants in the face-to-face group spent 238 minutes (median 103.3% of intended treatment time, IQR 150%-330%). Within the blended group, adherence to the face-to-face mode was twice as high as that to the web mode. Participants in the blended group spent an average of 198 minutes (SD 120) in face-to-face mode (152% of the intended treatment time) and 75 minutes (SD 53) in web mode (75% of the intended treatment time). Higher age was the only characteristic consistently found to uniquely predict higher adherence in both the blended and face-to-face groups. For the face-to-face group, more social support for smoking cessation was also predictive of higher adherence. The variability in adherence explained by these predictors was rather low (blended R2=0.049; face-to-face R2=0.076). Within the blended group, living without children predicted higher adherence to the face-to-face mode (R2=0.034), independent of age. Higher adherence to the web mode of the blended treatment was predicted by a combination of an extrinsic motivation to quit, a less negative attitude toward quitting, and less health complaints (R2=0.164).

CONCLUSIONS

This study represents one of the first attempts to thoroughly compare adherence and predictors of adherence of a blended smoking cessation treatment to an equivalent face-to-face treatment. Interestingly, although the overall adherence to both treatments appeared to be high, adherence within the blended treatment was much higher for the face-to-face mode than for the web mode. This supports the idea that in blended treatment, one mode of delivery can compensate for the weaknesses of the other. Higher age was found to be a common predictor of adherence to the treatments. The low variance in adherence predicted by the characteristics examined in this study suggests that other variables such as provider-related health system factors and time-varying patient characteristics should be explored in future research.

INTRODUCTION

As smoking remains the leading cause of preventable death, cessation treatment is pivotal for public health promotion (WHO, 2017). The introduction of eHealth (Oh, Rizo, Enkin, & Jadad, 2005) represents the expectation of information and communication technologies to improve health care (Alvarez, 2002). However, adherence is generally low in web-based treatment (Erbe, Eichert, Riper, & Ebert, 2017) as well as in cessation treatment in general (Kemmeren et al., 2016b). Low adherence is problematic because adherence has been shown to be an indicator of treatment's acceptability and a determinant of treatment's effectiveness (Alterman, Gariti, Cook, & Cnaan, 1999; Fish et al., 2009; Sabaté, 2003; Westman, Behm, Simel, & Rose, 1997). Therefore, adherence should be optimized because—assuming a dose-response relationship (Siemer et al., 2018)—patients are more likely to quit smoking if they are more exposed to active ingredients of the treatment (Sabaté, 2003). Adherence in general can be defined as the extent to which a person's behavior (eg, taking medication, following a diet, or executing lifestyle changes) corresponds with recommendations from a health care provider (Sabaté, 2003). In the context of behavioral change treatments, such as smoking cessation, adherence issues are mainly related to premature termination of treatment and failure to perform tasks and exercises between sessions (Bosworth, 2010).

BLENDED TREATMENT

The past decades, a variety of effective interventions for smoking cessation have become

available (Lancaster & Stead, 2017; Stead, Koilpillai, Fanshawe, & Lancaster, 2016), including more recently eHealth services such as for example web-based interventions (Civljak, Stead, Hartmann-Boyce, Sheikh, & Car, 2013; Taylor et al., 2017) or mobile-phone interventions (Whittaker et al., 2009; Whittaker, McRobbie, Bullen, Rodgers, & Gu, 2016). At present, traditional face-to-face (F2F) interventions on the one hand and both web-based and mobile-phone interventions on the other hand are increasingly being transferred to blended treatment. Blended treatment is a promising eHealth service, because it is expected that the strengths of one mode of delivery will compensate for the weaknesses of the other (Barak, Hen, Boniel-Nissim, & Shapira, 2008; Erbe et al., 2017; Kemmeren et al., 2016a; Postel, Witting, & Gemert-Pijnen, 2013; Siemer et al., 2016; van der Vaart et al., 2014; Wentzel, van der Vaart, Bohlmeijer, & van Gemert-Pijnen, 2016). The main strength of F2F-treatment is to provide personal attention of a professional, which could compensate for the lack of F2F-contact in web-based treatment. In turn, a main feature of web-based care is the accessibility anytime and anywhere which could compensate for time between F2F-sessions when patients need support. Blended treatment is applied in diverse settings (e.g. individual vs. group setting (Schuster, Leitner, Carlbring, & Laireiter, 2017)), addresses several health issues (e.g. depression (Kooistra et al., 2014), anxiety (Bruinsma, Kampman, Exterkate, & Hendriks, 2016), or addiction (Siemer et al., 2018; Siemer et al., 2016)), uses various tools (e.g. web platforms, emails, SMS, APPs (Kemmeren et al., 2016a; Kleiboer et al., 2016)), and uses different modes of delivery (e.g. mainly web-based (Harrington et al., 2012; Massoudi et al., 2017) vs. mainly face-to-face (Bruinsma et al., 2016; Mansson, Skagius Ruiz, Gervind, Dahlin, & Andersson, 2013) ; or integrated (Siemer et al., 2018; Siemer et al., 2016) vs. sequential (Harrington et al., 2012)). Since a clear definition of blended interventions is still missing (Wentzel et al., 2016), in this paper we define blended treatment as a combination of face-to-face sessions and web-based sessions to an integrated treatment which can be delivered by healthcare professionals on an outpatient basis. The blended intervention in this study is an integrated 50-50 blend of F2F-treatment and treatment via an online platform.

ADHERENCE TO BLENDED TREATMENT

Blended treatment has shown to positively influence adherence (Erbe et al., 2017; Hantsoo, Epperson, Thase, & Kim, 2013; Kay-Lambkin, Baker, Lewin, & Carr, 2011; Wilhelmsen et al., 2013). However, to the best of our knowledge, no studies to date have directly compared adherence to a blended treatment with adherence to either a web-based treatment or a face-to-face treatment with identical active components. In this study, we used data from the LiveSmokefree study(Siemer et al., 2016) which is a randomized controlled trial (RCT) comparing the effectiveness of a blended face-to-face and web-based smoking cessation treatment to a comparable face-to-face treatment. In a prior study, we explored measurement methods and levels and predictors of adherence to the blended treatment

by including the blended treatment group participants of the RCT only (Siemer et al., 2018). In the current study, we extended this previous work by including participants from the face-to-face treatment, allowing for a direct comparison of the levels of adherence between blended and face-to-face treatments. Furthermore, to explore whether both modes of delivery within the blended treatment were used in equal frequency, we also focused on levels of adherence within the blended group in the two modes.

PREDICTORS OF ADHERENCE

When adherence is low, adherence predictors become an area of interest because they may provide insight into the cause of low adherence and can help to generate new approaches to improving treatment or better alignment between the patient and treatment. Adherence, in general, is determined by provider behaviors, health system factors, and patient characteristics, and the latter have been most extensively examined as predictors of adherence to traditional interventions (Sabaté, 2003). Within the context of smoking cessation treatment—including both face-to-face and web-based treatments—several demographic, smoking-related, and health-related predictors of adherence have been examined. To date, several studies have indicated that the likelihood of being adherent may increase with a higher age (Ben Taleb, Ward, Asfar, Bahelah, & Maziak, 2015; Hays, Leischow, Lawrence, & Lee, 2010), male gender (Ben Taleb et al., 2015), higher internet skills (Gerhards et al., 2011; Mathew, Morrow, Frierson, & Bain, 2011), negative attitude toward smoking and higher motivation to quit at baseline (Asfar, Al Ali, Rastam, Maziak, & Ward, 2014; Heffner, Lewis, & Winhusen, 2013), higher self-efficacy at baseline (Heffner et al., 2013), early success in quitting after the start of the treatment (Alterman et al., 1999; Busnello et al., 2001; Hays et al., 2010), and lower nicotine dependency at baseline and fewer withdrawal symptoms after quitting (Asfar et al., 2014; Ben Taleb et al., 2015). For blended treatment, our previous study showed that higher adherence was best predicted by marital status (ie, having a partner) and social modeling (ie, more nonsmoking friends/partner) (Siemer et al., 2018). Building on this work, we have expanded on these previous findings in the current study by examining the predictors for adherence to both treatment arms (blended and face-to-face) and additionally the two modes of delivery (face-to-face mode and web mode) in the blended arm.

OBJECTIVES

In detail, this study explored the following questions. With respect to adherence, we asked (1) how adherent are participants to blended compared to face-to-face treatment? and (2) within the blended treatment group, how adherent are the participants to the face-to-face mode compared to the web mode? With respect to predictors, we asked (1) which demographic, smoking-related, and health-related patient characteristics predict adherence to blended and to face-to-face treatments, and to both groups combined? and (2) within the

blended group, which of these characteristics predict adherence to the face-to-face mode and to the web mode?

METHODS

STUDY SUBJECTS

In this study, we used the already available data from patients (blended n=130; face-to-face n=162) of a not yet completed nonblinded RCT on the effectiveness of a blended smoking cessation treatment compared with a face-to-face treatment (LiveSmokefree study, n=172 allocated per group to determine a difference in abstinence rates of 5 percentage points with a power of 80% and =.025) (Siemer et al., 2016). The patients were referred to the outpatient smoking cessation clinic at Medical Spectrum Twente hospital (Enschede, the Netherlands) by the treating physicians of the hospital or by their general practitioners, and attended the initial treatment session between May 2015 and September 2018. Inclusion criteria were: (1) willing to quit smoking, (2) aged 18 or older, and (3) current daily smoker (at least one cigarette a day). Exclusion criteria were: (1) no internet access (ie, email, websites) and (2) not able to read or write in the Dutch language. In line with the Dutch Medical Research Ethics Committee guidelines, the study was approved by the accredited MEC Twente (P14-37/NL50944.044.14). Before initiation, the study was registered in the Netherlands Trial Registry (NTR5113). All patients had to sign an informed consent form before they were randomized.

RANDOMIZATION

Patients were randomly assigned to either the blended or face-to-face group. Randomization was performed at the individual level (allocation ratio 1:1) using QMinim Online Minimization (Saghaei & Saghaei, 2011). The minimization was stratified according to: (1) level of internet skills (van Deursen, Courtois, & van Dijk, 2014); (2) level of nicotine dependence (Fagerstrom) (A. Mudde, Willemsen, Kremers, & de Vries, 2006; A. N. Mudde, 2000); and (3) the quitting strategy favored by the patient (stop at once, gradual change, scheduled reduced smoking; for details see below the description of the study intervention). The data used for QMinim minimization were collected using the baseline questionnaire completed online by the patient at home prior to the start of treatment.

STUDY INTERVENTIONS

The study interventions to be compared were a blended face-to-face and web-based smoking cessation treatment and a face-to-face treatment alone. Except for the differences in mode of delivery (ie, face-to-face mode and web mode), both treatments included the following same features: (1) high-intensity treatments comprising 10 sessions with a total treatment time of 230 minutes (20 minutes each, except for the first that was 50 minutes); (2) delivered by health care professionals in an outpatient cessation clinic; (3) derived from the Dutch Guideline for Tobacco Addiction (Partnership Stop met Roken, 2009a) fulfilling the requirements of the Dutch care module for smoking cessation (Partnership Stop met Roken, 2009b); (4) executed by counselors registered in the Dutch quality register of qualified smoking cessation counselors; (5) treatment costs reimbursed by the patient's health insurance; (6) supporting three quitting strategies that were chosen at the start of the treatment (stop at once, change gradually by increasing the number of daily activities that are performed smoke-free, or decrease smoking at regular intervals such as scheduled smoking reduction 100%-75%, 75%-50%, etc). The chosen quitting strategy did not influence the course of the treatment in general. The order, pace, duration, and intensity were the same for all strategies.

Both the blended and face-to-face treatments included the following behavior change techniques, according to BCT taxonomy v1 of Michie et al (Michie et al., 2013)): 1.1 Goal setting (behavior), 1.2 Problem solving, 1.3 Goal setting (outcome), 1.4 Action planning, 1.5 Review behavior goal(s), 1.6 Discrepancy between current behavior and goal, 1.8 Behavioral contract, 1.9 Commitment, 2.3 Self-monitoring of behavior, 2.4 Self-monitoring of outcome(s) of behavior, 2.6 Biofeedback, 2.7 Feedback on outcome(s) of behavior, 3.1 Social support (unspecified), 4.2 Information about antecedents, 4.3 Reattribution, 5.1 Information about health consequences, 5.2 Salience of consequences, 5.3 Information about social and environmental consequences, 5.4 Monitoring of emotional consequences, 5.5 Anticipated regret, 5.6 Information about emotional consequences, 6.2 Social comparison, 6.3 Information about others' approval, 7.4 Remove access to the reward, 8.1 Behavioral practice/rehearsal, 8.2 Behavior substitution, 8.3 Habit formation, 8.4 Habit reversal, 8.6 Generalization of a target behavior, 8.7 Graded tasks, 9.1 Credible source, 9.2 Pros and cons, 9.3 Comparative imagining of future outcomes, 10.7 Self-incentive, 10.9 Self-reward, 11.1 Pharmacological support (eg, nicotine replacement therapy [patches, gum], bupropion, varenicline), 11.2 Reduce negative emotions, 12.1 Restructuring the physical environment, 12.2 Restructuring the social environment, 12.3 Avoidance/reducing exposure to cues for the behavior, 12.4 Distraction, 13.1 Identification of self as role model, 13.2 Framing/reframing, 13.5 Identity associated with changed behavior, 14.4 Reward approximation, 14.5 Rewarding completion, 14.6 Situation-specific reward, 14.7 Reward incompatible behavior, 14.8 Reward alternative behavior, 15.1 Verbal persuasion about capability, 15.3 Focus on past success, and 16.3 Vicarious consequences.

The face-to-face treatment consisted of 10 face-to-face sessions delivered at the outpatient smoking cessation clinic. The blended treatment comprised 5 face-to-face sessions at the outpatient clinic and 5 web-mode sessions delivered via an online treatment platform. Both the face-to-face and blended treatments consisted of both counselor-dependent and counselor-independent components. The counselor-dependent web-based components

of the blended treatment were interactive and relied on (asynchronous) communication (email, messaging) between the counselor and participant. The counselor-independent components such as psychoeducational content or a smoking diary were used by the participants on their own and in their own time. In the face-to-face group, these components were provided in a paper manual that the participants took home. In the blended treatment, these components were accessible online. As such, both treatments were equivalent with regard to content and intensity. An additional benefit of the blended treatment was that the content of previous counselor-dependent components remained accessible as email and messaging correspondence saved online.

The most characteristic feature of the blended treatment examined in this study is an equal balance between the face-to-face and web mode sessions; that is, the focus of the treatment is neither on face-to-face mode nor web mode. In addition, there is constant alternation and interactive use of the two modes. Table 11 shows the order, timing, main features, duration, and modes of delivery of the treatment sessions in the face-to-face and blended treatments. Although an equal distribution was planned for the blended treatment with regard to the number of sessions, there was an uneven distribution for the duration of treatment because the first session (50 minutes for face-to-face mode) was longer than the remaining sessions (20 minutes for the face-to-face mode or 20 minutes for web mode); therefore, the participants in the blended group spent 130 minutes in face-to-face mode and 100 minutes in web mode.

TABLE 11. Order, timing, main features, duration, and mode of delivery of the treatment sessions in F2F and BSCT according to treatment protocol

Session	Week	Main features	Duration (min)	Mode of delivery	
				BSCT	F2F
			230	130 min F2F-mode 100 min Web-mode	230 min F2F-mode
1	1	Goal setting; Prompt smoking diary; Measure CO[b]	50	F2F-mode[a]	F2F-mode
2	3	Measures for self-control	20	Web-mode[c]	F2F-mode
3	5	Dealing with withdrawal	20	F2F-mode	F2F-mode
4	7	Breaking habits	20	Web-mode	F2F-mode
5	9	Dealing with triggers	20	F2F-mode	F2F-mode
6	11	Food for thought	20	Web-mode	F2F-mode
7	14	Think differently; Measure CO	20	F2F-mode	F2F-mode
8	18	Do differently	20	Web-mode	F2F-mode
9	22	Action plan; Measure CO	20	F2F-mode	F2F-mode
10	26	Closure	20	Web-mode	F2F-mode

[a]F2F-mode, face-to-face treatment session of the blended smoking cessation treatment
[b]CO, Carbon monoxide measurement
[c]Web-mode, web-based sessions of the blended smoking cessation treatment

A detailed description of the treatments can also be found in the protocol article of the RCT (Siemer et al., 2016) and in the description of the user experience of the blended smoking cessation treatment (Siemer, Ben Allouch, et al., 2019b). Screenshots of the web sessions of the blended treatment are shown in “Multimedia Appendix 1: Screenshots of the Web-Sessions of BSCT” to provide an impression of the look and feel of the web interventions.

DATA COLLECTION

Patients’ characteristics

As part of the RCT (LiveSmokefree-study), 33 demographic, smoking-related, and health-related characteristics were assessed with the intake measurement using an online questionnaire. A detailed description of these characteristics is available in the protocol article of the RCT (Siemer et al., 2016).

Measuring adherence

Established measures for adherence to a blended treatment are still lacking. Therefore, for the 2018 study (Siemer et al., 2018), we constructed a customized measure for adherence by selecting 18 patient activities (eg, using a web-based smoking diary tool, responding to counselors’ messages) to trace adherence to the blended treatment. Adequacy of this adherence measure was confirmed by the observed dose-response relationship between adherence and the likelihood of quitting, which is consistent with the smoking cessation literature (Alterman et al., 1999; Fish et al., 2009; Sabaté, 2003; Westman et al., 1997). However, this activity-based method was quite detailed and labor-intensive and was particularly interesting from a methodological point of view. Since the current study was mainly focused on comparing treatment modalities in a clinical context, we used a simpler time-based method for measuring adherence, which was proven to be as suitable for clinical research as the activity-based method and was also found to be more efficient (Siemer, Brusse-Keizer, et al., 2019a, 2019b). Although this time-based method was not as accurate as the activity-based method, it was applicable in this case because the primary goal of this study was to determine differences between the groups in terms of levels and predictors of adherence. Therefore, the analysis of relative level differences was more relevant than an exact measurement of absolute levels. Furthermore, the time-based method allowed for analysis of a larger sample and thus more accurate statistics, as it required less time and money.

For this time-based approach, we used treatment data from the hospital’s electronic patient record system. This record system contains basic information of the patients’ treatment status such as when the patient started treatment; which counselor was offering the treatment; time, day, and type of appointments; time and day of telephone consults; and which kind of treatment was offered in each appointment (Patrinopoulos Bougioukas, 2017). In this record system, the counselors reported, in an encoded form, which type of sessions

were completed. Each code represents a fixed, average number of minutes invested in face-to-face mode or web mode, as shown in Table 12. These fixed numbers of minutes per sessions were used to calculate the total number of minutes in treatment for each patient for the blended and face-to-face treatments, as well as for the face-to-face mode and web mode in the blended treatment.

TABLE 12. Codes, descriptions, modes of delivery, and duration of F2F and BSCT sessions used to measure adherence

Code	Description of the type of session	Mode	Minutes
RSN	First individual F2F session at treatment start	F2F-mode[a]	50
RSAB	Like RSN, but visiting a patient at another department of the hospital	F2F-mode	50
RSNS	Like RSN, but with two patients at the same time (e.g. husband and wife)	F2F-mode	35
RSC	Usual individual F2F session	F2F-mode	20
RSAC	Additional consult (to add to RSN/RSAB/RSNS/RSC if more time is needed)	F2F-mode	20
RSTC	Individual telephone consult	F2F-mode	20
RSOC	Any other individual consult	F2F-mode	10
RSIC	Web-mode treatment session via rokendebaas.nl	Web-mode[b]	20
RSEC	Email consulting	Web-mode	10

[a]F2F-mode, face-to-face treatment session of the blended smoking cessation treatment
[b]Web-mode, web-based sessions of the blended smoking cessation treatment

5

STATISTICAL ANALYSIS

All analyses were performed using SPSS version 24.

Patients' characteristics

For both the blended and face-to-face groups, 33 demographic, smoking-related, and health-related characteristics were measured and are reported as means (SDs) for normally distributed continuous variables and as medians (IQRs) for nonnormally distributed continuous variables. Categorical variables are reported as numbers with corresponding percentages. To identify between-group differences within the 33 demographic, smoking-related, and health-related patient characteristics, independent *t* tests or Mann-Whitney *U* tests were performed as appropriate for continuous variables; the Pearson Chi-square or Fisher exact test was performed for categorical variables.

Adherence (time spent in treatment)

Based on the hospital administrational records, both the absolute treatment time (in minutes) and the proportional treatment time (in percentage) of the patients who had started treatment were calculated for the blended and face-to-face groups, as well as for the face-to-face mode and web mode of the blended treatment. Bar charts were used to compare how

many patients spend how much time in the blended and face-to-face treatment on the one hand and in each mode of the blended treatment on the other hand. Mann Whitney *U* tests were performed to compare the absolute treatment time of the blended and face-to-face treatments and the proportional treatment time for the face-to-face and web modes in the blended treatment.

Predictors of adherence

To identify the predictors of adherence (as a continuous variable) within the 33 demographic, smoking-related, and health-related patient characteristics, Pearson or Spearman correlation tests were performed as appropriate for continuous variables; independent *t* tests or Mann-Whitney *U* tests were performed for dichotomous variables. Variables with significance at $P<.15$ were considered as candidates for multivariate linear regression analyses. They were first tested with univariate linear regression analyses so that univariate and multivariate odds ratios could be compared, and were entered in the multivariate linear regression analyses after checking for multicollinearity. The variables were either all entered and removed step by step via the backward selection method (all patients; blended group; face-to-face group; face-to-face mode of the blended treatment) or entered step by step via the forward selection method (web mode of the blended treatment). Variables were entered or eliminated step by step based on the model fit. In the case of multicollinearity, the variable with the best model fit was selected for linear analyses.

RESULTS

5

PARTICIPANT FLOW

Figure 3 shows the flow of participants through the study. A total of 292 patients were eligible for the study, provided written consent, filled out the baseline questionnaire, and were randomized (blended n=130; face-to-face n=162). Before the start of treatment, 7/130 (5.4%) patients of the blended group and 6/162 (3.7%) patients of the face-to-face group withdrew. Finally, data from 123/130 (94.6%) patients in the blended group and 156/160 (96.3%) patients in the face-to-face group were available for adherence analysis.

PATIENTS' CHARACTERISTICS

Table 13 shows the patients' characteristics for both the BSCT group (N=130) and the F2F group (N=162). For six of the 33 characteristics significant ($P<.05$) differences between the BSCT and F2F group were found. Patients in the F2F group had higher internet skills, used more medication in general, reported less health complaints, and scored higher on the DASS subscales depression-, anxiety-, and on the total-score.

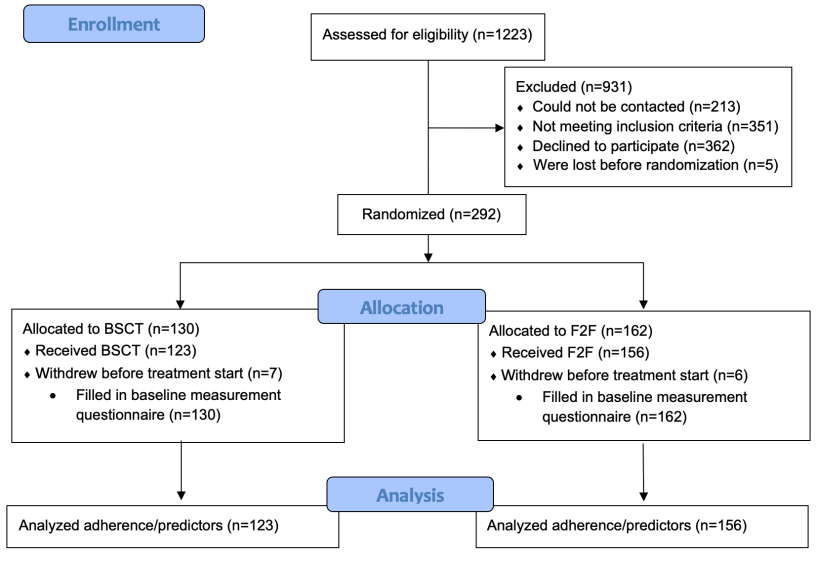

FIGURE 3. Flow of participants through the study. Bsct: blended smoking cessation treatment; f2f: face-to-face.

TABLE 13. Patients' characteristics of both the blended smoking cessation treatment (BSCT) and face-to-face (F2F) groups.

Characteristic		BSCT (N=130)	F2F (N=162)	*P*
Demographic				
Sex	Female (%[b])	62 (47.7)	77 (47.5)	.98
Age	Years, mean (SD[d])	47.1 (12.8)	46.6 (13.2)	.76
Marital status	With partner (%)	87 (66.9)	96 (59.3)	.18
	Alone (%)	43 (33.1)	66 (40.7)	
Housing situation	Children (%)	54 (41.5)	65 (40.9)	.91
	No children (%)	76 (58.5)	94 (59.1)	
Education	VET[e] or higher (%)	82 (63.1)	101 (63.9)	.88
	Lower than VET (%)	48 (36.9)	57 (36.5)	
Main income	Wage or own company (%)	64 (48.2)	83 (51.2)	.73
	Income support (%)	66 (50.8)	79 (48.8)	
Main day activity	Paid work (%)	61 (46.9)	79 (49.1)	.72
	Other (%)	69 (53.1)	82 (50.9)	
Internet skills[f]	Mean (SD)	38.5 (5.64)	40.52 (8.63)	.01
Smoking-related				
Reason to start treatment	Intrinsic (%)	83 (63.8)	107 (66.0)	.70
	Extrinsic (%)	47 (36.2)	55 (34.0)	
Nicotine dependency[g]	Mean (SD)	5.29 (2.10)	5.00 (2.18)	.59
Negative attitude towards quitting[h]	Mean (SD)	-5.70 (3.16)	-5.00 (2.96)	.07
Positive attitude towards quitting[i]	Median (IQR[c])	10 (8-12)	10 (8.75-11)	.91
Self-efficacy[j]	Mean (SD)	-.37 (5.32)	-.45 (5.02)	.89
Readiness to quit[k]	Median (IQR)	2 (1-3)	2 (1-3)	.31

TABLE 13 continued.

Characteristic		BSCT (N=130)	F2F (N=162)	*P*
Smoking-related				
Earlier quit attempts	Yes (%)	108 (83.1)	143 (88.3)	.20
Social support[l]	Median (IQR)	4 (3-5)	4 (3-5)	.99
Social modelling[m]	Median (IQR)	3.5 (1-6)	3 (1-5)	.13
Use of alcohol[n]	Median (IQR)	2 (1-3)	2 (0.75-3)	.26
Use of (recreational) drugs	Yes (%)	11 (8.5)	14 (8.7)	.94
Health-related				
Use of medication in general	Yes (%)	85 (65.4)	123 (75.9)	.05
Use of medication for addiction treatment	Yes (%)	0 (0.00)	0 (0.00)	[a]
Use of medication for psychiatric treatment	Yes (%)	26 (20.0)	23 (15.1)	.28
Use of medication for physical treatment	Yes (%)	64 (49.2)	88 (57.9)	.15
Use of other medication	Yes (%)	19 (14.6)	31 (20.4)	.21
Health complaints (MAP HSS)[o]	Mean (SD)	12.58 (6.27)	10.96 (7.17)	.04
Smoking related complaints[p]	Mean (SD)	20.82 (9.17)	19.95 (8.86)	.41
Health and smoking related complaints[q]	Mean (SD)	33.56 (13.87)	30.91 (14.42)	.11
Depression[r]	Median (IQR)	4 (0-10)	4 (2-24)	.02
Anxiety[r]	Median (IQR)	4 (2-8)	6 (2-16.5)	.002
Stress[r]	Median (IQR)	8 (4-16)	10 (4-14)	.73
DASS[s]	Median (IQR)	18 (8-32)	22 (8-58.5)	.01
EQ-5D-3L[t]	Median (IQR)	0.77 (0.69-1.00)	0.77 (0.69-1.00)	.42
EQ VAS[u]	Mean (SD)	66.95 (16.88)	65.17 (17.56)	.38

[a] no statistics are computed because variable is a constant
[b]%, percentage
[c]IQR, inter quartile range
[d]SD, standard deviation
[e]VET, vocational education and training
[f]Internet skills (range 10 - 60; higher number indicates better skills)
[g]Nicotine dependency (Fagerstroem) (range 0 - 10; higher numbers indicate higher nicotine dependency)
[h]Negative attitude towards quitting (range -12 - 0; lower numbers indicate a more negative attitude towards quitting smoking)
[i]Positive attitude towards quitting (range 0 - 12; higher numbers indicate a more positive attitude towards quitting smoking)
[j]Self-efficacy (range -12 - 12; higher numbers indicate higher self-efficacy related to smoking cessation)
[k]Readiness to quit (range 0 – 4: higher numbers indicate higher readiness to quit)
[l]Social support (range 0 – 5; higher numbers indicate more social support in smoking cessation)
[m]Social modelling (range 0 – 8; higher numbers indicate more smokers in the social environment)
[n]Use of alcohol (range 0 -4; higher numbers indicate higher alcohol consumption)
[o]Health complaints (MAP HSS), Maudsley Addiction Profile Health Symptoms Scale (range 0 – 40; higher numbers indicate poorer health status)
[p]Smoking related complaints (range 0 - 64; higher numbers indicate more smoking related complaints)
[q]Health and smoking related complaints (range 0 – 104; higher numbers indicate poorer health status and more smoking related complaints)
[r]Depression/Anxiety/Stress (range 0 – 42; higher number indicate a higher level of depression/anxiety/stress)
[s]DASS, sum score of Depression/Anxiety/Stress (range 0 – 126; higher numbers indicate a more negative emotional status)
[t]EQ-5D-3L, societal-based quantification of the patients' health status (range 0 – 1; higher numbers indicate better health status)
[u]EQ VAS, visual analogue scale for quality of life (range 0 – 100, higher numbers indicate better state of health)

ADHERENCE (TIME SPENT IN TREATMENT)

As illustrated in Figure 4, adherence to the blended and face-to-face treatments was comparable. Patients in the blended group (n=123, 7 patients dropped out between inclusion and the first treatment session) spent a median of 246 (IQR 150-355) minutes in treatment (106.7% of the intended total treatment time); in the face-to-face group (n=156, 6 patients dropped out between inclusion and first treatment session), the patients spent a median of 238 (IQR 150-330) minutes in treatment (103.3% of the intended total treatment time). There was no significant difference between the two groups (*P*=.30).

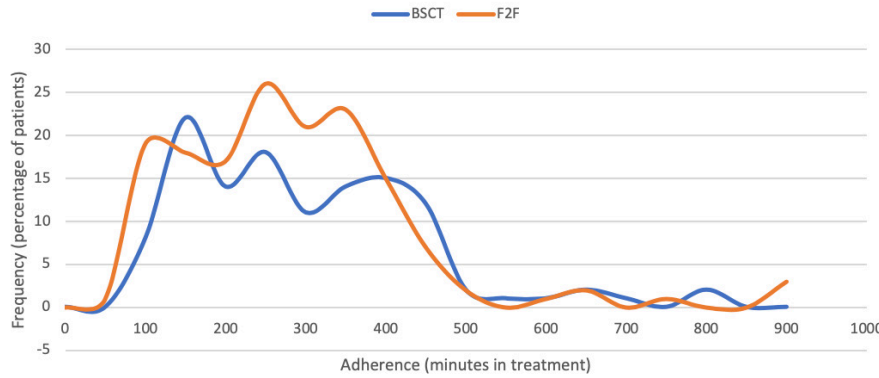

FIGURE 4. Adherence to blended smoking cessation treatment (BSCT) vs face-to-face (F2F) treatment.

However, within the blended group, as shown in Figure 5, patients were more adherent to the face-to-face mode than to the web mode. Patients in the blended group (n=123) spent a mean of 198 (SD 120) minutes in face-to-face mode and 75 (SD 53) minutes in web mode. In proportion to the intended treatment time for each mode of delivery (face-to-face mode=130 minutes; web mode=100 minutes), patients in the blended group spent twice the time in face-to-face mode (mean 152%, SD 92% of 130 minutes) than in web mode (mean 75%, SD 53% of 100 minutes) (t_{122}=10.03; *P*<.001).

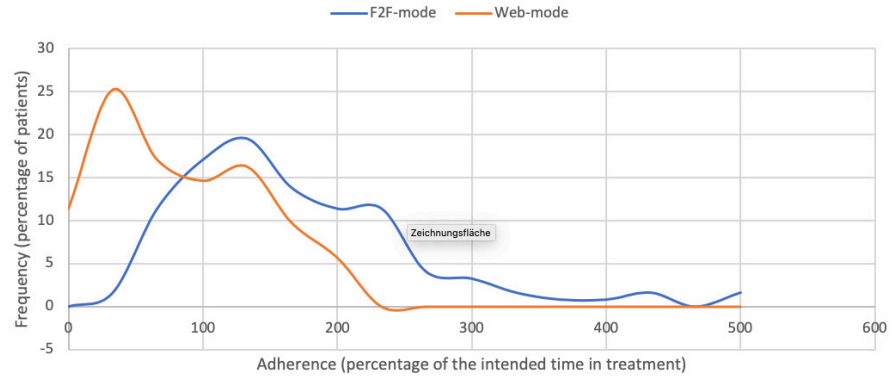

FIGURE 5. Adherence within the blended smoking cessation treatment group to the two modes of the treatment: face-to-face (F2F) mode vs web mode.

PREDICTORS OF ADHERENCE

For both treatments together, 7 predictors (Table 14) were significantly associated with higher adherence in the univariate analysis (assessed at *P*<.15), including male sex, older age, housing situation (living without children), higher readiness to quit, higher social support, lower social modeling (less smokers in the social environment), and higher use of other medication. Multivariate regression analyses (Table 15) revealed that age was the best predictor of adherence (R^2=0.047). Per life year, patients spent 2.5 more minutes in treatment (95% CI 1.2-3.8; *P*=.001).

For the face-to-face group, 6 predictors (Table 14) were significantly associated with higher adherence in the univariate analyses (assessed at *P*<.15), including older age, higher readiness to quit, more social support, lower social modeling, higher use of other medication, and higher smoking-related complaints. Multivariate regression analyses (Table 15) revealed that age and social support together were the best predictors of adherence (R^2=0.076). Per life year, patients spent 2.2 minutes more in treatment (95% CI 0.4-3.9; *P*=.02). For social support, graded from 0 (low social smoking cessation support) to 5 (high social smoking cessation support), each unit increase was associated with 20.5 more minutes in treatment (95% CI 2.3-38.8; *P*=.03).

TABLE 14. Univariate predictors for adherence in all patients and in each treatment group.

Characteristic		All patients		F2F[a]		BSCT[b]	
		Regression coefficient (95% CI)	*P* value	Regression coefficient (95% CI)	*P* value	Regression coefficient (95% CI)	*P* value
Sex		.11		– [e]		–	
	Female (reference)	N/A[c]		–		–	
	Male	28.6 (–6.4-63.6)		–		–	
Age (years)		2.5 (1.2-3.8)	.001	2.4 (0.7-4.2)	.01	2.6 (0.5-4.6)	.01
Housing situation			.13		–		.05
	Children (reference)	N/A		–		–	
	No children	27.8 (–8.0-63.6)		–		52.9 (105.6-0.4)	
Nicotine dependency		–	–	–	–	–10.9 (–23.3-1.4)	.08
Negative attitude toward quitting		–	–	–	–	6.6 (–1.6-14.7)	.11
Readiness to quit		16.0 (–1.5-33.6)	.07	21.1 (–3.3-45.5)	.09	–	–
Social support		13.6 (0.5-26.8)	.04	23.3 (4.5-41.7)	.01	–	–
Social modeling		–8.4 (–15.5 to –1.5)	.02	–10.1 (–20.0 to –0.1)	.05	–7.5 (–17.1-2.2)	.13
Use of other medication			.06		.06		–
	Yes (reference)	N/A		N/A		–	
	No	–36.8 (–75.0-1.3)		–53.2 (–108.1-1.7)		–	
Health complaints (MAPHSSd)		–		–		–3.4 (–7.5-0.7)	.10
Smoking-related complaints		–		2.20 (–0.5-4.9)	.10	–	
Anxiety		–		–		–3.5 (–8.0-0.9)	.12
Stress		–		–		–2.8 (–6.2-0.6)	.11

[a]F2F: face-to-face treatment group.
[b]BSCT: blended smoking cessation treatment group.
[c]N/A: not applicable.
[d]MAPHSS: Maudsley Addiction Profile Health Symptoms Scale.
[e] not available, since for the sake of clarity only those variables are presented in this table that were included in the multivariate regression due to P<.015.

TABLE 15. Multivariate model of patient characteristics predicting adherence for all patients and each treatment group.

Variable	All patients	F2F[a]	BSCT[b]			
	Regression coefficient (95% CI)	*P*	Regression coefficient (95% CI)	*P*	Regression coefficient (95% CI)	*P*
Age (years)	2.5 (1.2-3.8)	.001	2.2 (0.4-3.9)	.02	2.6 (0.5-4.6)	.01
Social support	-[c]	-	20.5 (2.3-38.8)	.03	-	-

[a]F2F: face-to-face treatment.
[b]BSCT: blended smoking cessation treatment.
[c]not available, as for the sake of clarity only the variables of the final models are presented here.

Fo

For the blended group, 8 predictors (Table 14) were significantly associated with higher adherence in the univariate analyses (assessed at *P*<.15), including higher age, housing situation (living without children), lower nicotine dependency (Fagerstroem), higher negative attitude toward quitting, lower social modeling, lower health complaints, lower anxiety, and lower stress. Multivariate regression analyses (Table 15) revealed that age was the best predictor of adherence (*P*=.01). Per life year, patients spent 2.6 more minutes in treatment (95% CI 0.5-4.6; R^2=0.049).

For the face-to-face mode of the blended treatment, 3 predictors (Table 16) were significantly associated with higher adherence in univariate analyses (assessed at *P*<.15), including higher age, housing situation (living without children), and lower internet skills (Table 16). Multivariate regression analyses (Table 17) revealed that housing situation was the best predictor of face-to-face mode adherence (R^2=0.034). Patients living without children spent 49.7 more minutes in the face-to-face mode of the blended treatment (95% CI 92.7-6.8; *P*=.02) (Table 17).

TABLE 16. Univariate predictors for adherence to face-to-face (F2F) mode and web mode in the blended treatment group.

Variable		F2F mode		Web mode	
		Regression coefficient (95% CI)	*P* value	Regression coefficient (95% CI)	*P* value
Sex					.12
	Female (reference)	N/A[a]		N/A	
	Male	- [e]		14.9 (33.8 to –3.9)	
Age		1.9 (0.2-3.6)	.03	0.8 (0.1-1.5)	.03
Housing situation			0.2		-
	Children (reference)	N/A		–	
	No children	49.7 (6.8 - 92.7)		–	
Main income			–		.07
	Wage or own company (reference)	–		N/A	
	Income support	–		–17.2 (–36.0 to –1.5)	
Main day activity			–		.02
	Paid work (reference)	–		Ref	
	Other	–		–21.7 (–40.3 to –3.1)	
Internet skills		–3.0 (–6.8-0.8)	.12	–	–
Reason to start treatment			–		.09
	Extrinsic (reference)	–		N/A	
	Intrinsic	–		–16.9 (–36.4-2.5)	
Nicotine dependency		–	–	–6.1 (–10.5 to –1.8)	.01
Negative attitude towards quitting		–	–	3.8 (0.9-6.7)	.01
Self-efficacy		–	–	1.4 (–0.3-3.2)	.12
Social modeling		–	–	–3.1 (–6.6-0.4)	.08
Health complaints (MAPHSS[b])		–	–	–2.4 (–3.8 to –0.9)	.001

TABLE 16 continued.

Variable	F2F mode Regression coefficient (95% CI)	*P* value	Web mode Regression coefficient (95% CI)	*P* value
Reason to start treatment				.09
Smoking related complaints	–	–	–1.0 (–2.0-0.1)	.06
Health and smoking related complaints	–	–	–0.9 (–1.6 to –0.3)	.01
Anxiety	–	–	–2.2 (–3.7 to –0.6)	.01
Stress	–	–	–1.4 (–2.6 to –0.2)	.03
DASS[c]	–	–	–0.6 (–1.1 to –0.1)	.02
EQ-5D-3L[d]	–	–	28.9 (–8.1-65.8)	.13

[a]N/A: not applicable.
[b]MAPHASS: Maudsley Addiction Profile Health Symptoms Scale.
[c]DASS: Sum of Depression, Anxiety, and Stress scores.
[d]EQ-5D-3L: societal-based quantification of health status.
[e]not available, since for the sake of clarity only those variables are presented in this table that were included in the multivariate regression due to P<.015.

For the web mode of the blended treatment, 16 predictors (Table 16) were significantly associated with higher adherence in univariate analyses (assessed at *P*<.15), including male sex, older age, main income (income support), main day activity (other than paid work), extrinsic reason to start treatment, lower nicotine dependency (Fagerstroem), higher negative attitude toward quitting, higher self-efficacy, lower social modeling, lower health complaints (assessed on the Maudsley Addiction Profile Health Symptoms Scale [MAPHSS]), lower smoking-related complaints, lower health and smoking-related complaints, lower anxiety, lower stress, lower DASS, and higher quality of life (EQ-5D-3L). Health and smoking-related complaints and the DASS were not used for multivariate regression because of multicollinearity. Multivariate regression analyses (Table 17) revealed that reason to start treatment, negative attitude toward quitting, and health complaints (MAPHSS) together were the best predictors of web mode adherence (R^2=0.164). Patients with an intrinsic motivation spent 21.5 less minutes in the web mode of the blended treatment (95% CI –39.8 to –3.3; *P*=.02). For negative attitude toward quitting (range –12 to 0; lower numbers indicate a more negative attitude toward quitting smoking), each unit increase (ie, a less negative attitude) was associated with 3.6 more minutes in web mode of the blended treatment (95% CI 0.9-6.4, *P*=.01). For health complaints (range 0-40; higher numbers indicate poorer health status), each unit increase (ie, additional complaint reported) was associated with 2.4 less minutes in the web mode of the blended treatment (95% CI –3.8 to –1.0, *P*=.001).

TABLE 17. Multivariate model of patient characteristics predicting adherence to face-to-face (F2F) and web mode in the blended treatment group.

Variable		F2F mode Regression coefficient (95% CI)	*P* value	Web mode Regression coefficient (95% CI)	*P* value
Housing situation			.02		- [c]
	Children (reference)	N/A[a]		-	
	No children	49.7 (6.8-92.7)		-	
Reason to start treatment			-		.02
	Extrinsic (reference)	-		N/A	
	Intrinsic	-		–21.5 (–39.8 to –3.3)	
Negative attitude toward quitting		-	-	3.6 (0.9-6.4)	.01
Health complaints (MAPHSS[b])		-	-	–2.4 (–3.8 to –1.0)	.001

[a]N/A: not applicable.
[b]MAPHSS: Maudsley Addiction Profile Health Symptoms Scale.
[c]not available, as for the sake of clarity only the variables of the final models are presented here.

DISCUSSION

PRINCIPAL FINDINGS

Since the emergence of web-based health promotion counseling a few decades ago, blended treatments have recently been introduced. The aim of the present study was to directly compare adherence to a blended treatment with a face-to-face treatment for smoking cessation with similar content.

Based on the treatment times documented in the hospital administration, we found comparable adherence levels for the blended and face-to-face treatments. However, within the blended treatment, we found that patients spent twice as much time in face-to-face mode (152% of the intended treatment time) than in web mode (75% of the intended treatment time), suggesting a tendency to substitute web sessions by additional face-to-face sessions.

Older age was the only characteristic consistently found to predict higher adherence to both the face-to-face and blended treatments. For the face-to-face group, we found that both older age and perceived social support for smoking cessation predicted higher adherence. Age is known as a relevant demographic characteristic for predicting adherence (Ben Taleb et al., 2015; Hays et al., 2010), but more social support to quit smoking has not yet been indicated as an independent predictor of adherence.

Within the blended treatment, no consistent predictor of adherence was found for its

two modes of delivery. Higher adherence to the face-to-face mode was predicted by the housing situation (ie, living without children), whereas adherence to the web mode was predicted by an extrinsic motivation to quit, a less negative attitude toward quitting, and less health complaints. Although these models contained statistically significant predictive patient characteristics, the predicted proportion of variability in adherence was small, ranging from 3.4% to 16.4%. Thus, it seems immature to interpret these findings in an attempt to understand the mechanisms in adherence to blended smoking cessation treatment, and it is difficult to find a meaningful pattern in these predictors. To explain this low model fit, two aspects can be considered. First, this could indicate that the predictors examined in this study, namely only the patient characteristics, are not comprehensive. For example, it seems likely that provider-related variables and health care system factors such as treatment costs, failure to recall a receipt of a prescription, and access to free nicotine replacement therapy (Sabaté, 2003) also play a role. As no data on these factors were available in this study, this could not be further verified. Second, all patient-related predictors used in the current study were evaluated at the start of treatment, which means that changes in these characteristics during treatment (eg, due to negative treatment effects such as weight gain, adverse events, or withdrawal symptoms) were not considered. As an example of a positive treatment effect, in the context of smoking cessation treatment, the bidirectional relation between quitting success and adherence is known, in which early quitting success predicts higher adherence (Hays et al., 2010), while higher adherence predicts (long-term) abstinence (Alterman et al., 1999; Fish et al., 2009; Sabaté, 2003; Westman et al., 1997). Another example is the user experience that patients build during the course of treatment. Patients may experience the treatment as “useful,” “easy to follow,” or “stimulating” and adhere to the treatment accordingly (Siemer, Ben Allouch, et al., 2019a; Siemer, Ben Allouch, et al., 2019b).

In general, the finding for the blended group that treatment time not used in web mode was compensated by face-to-face mode treatment would support the expectation that in blended treatment, the strengths of one mode of delivery will compensate for the weaknesses of the other (Barak et al., 2008; Erbe et al., 2017; Kemmeren et al., 2016a; Postel et al., 2013; Siemer et al., 2016; van der Vaart et al., 2014; Wentzel et al., 2016). This expectation is also supported based on our recently published qualitative study on user experience with this blended smoking cessation treatment (Siemer, Ben Allouch, et al., 2019a; Siemer, Ben Allouch, et al., 2019b), in which we also found that the strengths of the face-to-face mode can compensate for the weaknesses of the web mode. It is noteworthy that this compensation is mainly unidirectional: face-to-face mode compensates or replaces web mode and not vice versa. By exceeding the planned face-to-face treatment time by 100 minutes on average, the vast majority of patients in the blended group (118/123, 95.9%) spent significantly more time in face-to-face mode than in web mode. By contrast, only 5/123 (4.1%) patients spent slightly more time (an additional 27 minutes on average) in web mode than in face-to-face mode. Perhaps the new and challenging web mode is not used optimally, as it can (easily) be compensated by the traditional, familiar face-to-face mode.

Although the main objective of this study was to provide a treatment time–based comparison of adherence, we would like to briefly mention two aspects that surprised us when comparing the results with one of our previous studies (Siemer et al., 2018) that used a different operationalization of adherence.

First, the current study revealed rather high adherence to both the blended and face-to-face treatments. Due to differences in interventions, measurements of adherence, adjunctive support, and investigated populations, adherence rates for smoking cessation treatment vary widely between different studies (5%-96%) (Sabaté, 2003). This makes it difficult to compare adherence rates in general. Moreover, little is known about adherence rates for blended treatment. We only found one study that reported adherence rates: in a blended depression treatment, adherence to the blended treatment (90.5%) and the face-to-face treatment (95.1%) was comparable (Wright et al., 2005)). Our study seems to agree with this previous study, as we also found comparably high adherence to the blended (106.7%) and face-to-face (103.3%) treatments. Surprisingly, for the blended treatment, the findings in this study seem to contradict our findings from a previous study among participants of the blended treatment in the same sample (Siemer et al., 2018), in which we reported that adherence to the blended treatment seemed rather low. These apparent contradictory results may be explained by different operationalizations of adherence and different measurement methods in the two studies. In the 2018 study, we traced treatment activities of the patients in detail (not only treatment time as used in the current study) and strived for a categorical threshold-based classification of patients as being either adherent or nonadherent. This activity-based method used in the 2018 study correlates with the time-based measurement applied in the current study, but it was more specific (Siemer, Brusse-Keizer, et al., 2019a, 2019b) and therefore resulted in lower absolute adherence rates (Siemer et al., 2018).

Second, in our 2018 study (Siemer et al., 2018), we found that in the blended treatment, based on patients’ activities, there was no significant difference in adherence to the face-to-face mode compared with the web mode. Surprisingly, in the current study, based on treatment time, the adherence levels differed significantly. Patients spent only 75.2% of the intended treatment time in the web mode, but 152.3% of the intended treatment time in the face-to-face mode. This shows that in practice it is rather a 2/3 to 1/3 ratio between face-to-face mode and web mode in the blended group than the planned equal ratio. This could mean, for example, that patients in face-to-face mode need more time than planned for

their activities, or that additional unplanned activities take place within the treatment time. This could be an indication of therapist drift—a known weakness of face-to-face treatment (Mansson et al., 2013) —and thus bring the topic of treatment fidelity into focus. From a clinical point of view, the question then arises as to whether the planned times for face-to-face mode and web mode are appropriate.

LIMITATIONS AND IMPLICATIONS FOR FUTURE WORK

To the best of our knowledge, this is the first study to compare adherence and predictors of adherence in patients randomly assigned to either a blended smoking cessation treatment or a face-to-face treatment with identical active components. Moreover, this is also the first study to compare adherence and predictors of adherence to the face-to-face mode with those to the web mode of a blended smoking cessation treatment. One limitation of this study is that the measurement of adherence was based on the treatment time documented in the hospital's administrational records, as this documentation is mainly used for financial accounting and therefore does not reflect in detail the contents and the exact temporal proportions of the treatments. Even though we assume that we have a sufficiently valid measure for the comparison of adherence and for the determination of predictors, these data unfortunately do not provide deeper insight into the adherence to the treatment process in detail. For example, the specific treatment activities carried out in different time frames remain unclear. In addition, the time data for the sessions were standard values and not exactly determined as treatment time per session. Individual sessions may therefore have been shorter or longer than evaluated. The absolute time values should therefore be interpreted with caution. Furthermore, in view of the differences between the results of this study and those of the 2018 study (Siemer et al., 2018), in which different operationalizations of adherence were applied (time-based vs activity-based), the methodological question also arises as to which operationalization best reflects adherence. From our previous studies (Siemer, Brusse-Keizer, et al., 2019a, 2019b) we know that activity-based measurement has better predictive validity, which makes it seem more adequate when adherence is considered a determinant of efficacy (dose-response relationship). In this study, however, we used a time-based measurement because it requires less financial and time effort, the possibility of analyzing a larger sample size allowed us to expect more accurate statistics, and because we wanted to gain more experience with its application in clinical practice. The differences found in adherence between the 2018 study and the present study bring forth an interesting issue that deserves more attention and should be targeted in future studies, such as by addressing the research questions of this study using activity-based measurement to analyze the entire sample.

Another limitation is the low variability of adherence explained by our prediction models. The question arises as to whether the chosen predictors and their measurement are sufficient. Future research should further investigate which additional predictors (eg, provider behavior, health system factors, or other patient characteristics) should be included and how these can be measured, not only at the beginning but also over the course of treatment, so that they fit optimally to the research question.

Another point of interest should be the difference in predictors and levels of adherence to the two modes of delivery in the blended treatment. The characteristics associated with adherence are quite different (adherence to the face-to-face mode of the blended treatment was mostly associated with demographic characteristics, whereas adherence to the web mode of the blended treatment was mainly associated with smoking-related and health-related characteristics). Future research should examine the causation of these differences. For example, it is possible that web-mode treatment is better suited for patients with less health complaints because they rely less on a hospital setting and the direct contact to a health care professional such as the smoking cessation counselor. Alternatively, web-mode treatment might be better suited for externally motivated patients because they already arrive at the treatment with a default desire to do what they are told and are therefore more likely to stick to the web mode.

Furthermore, the differences in the blended treatment adherence levels are noteworthy. In web mode, the adherence level was in the expected range, whereas there was overadherence found for the face-to-face mode. This could be related to the fact that the treatment basically starts with a rather long face-to-face session and therefore results in a type of face-to-face default mode. Therefore, it is possible that the result would have been different if the treatment had started in web mode. The overadherence raises another question as to which level of adherence is optimal to reach the treatment goals; that is, is higher adherence (152% adherence to face-to-face mode) better than lower adherence (ie, 75% adherence to web mode)?

CONCLUSION

This study represents one of the first attempts to thoroughly compare adherence and predictors of adherence of a blended smoking cessation treatment to a face-to-face treatment. Our results showed that the levels of adherence to both treatments were comparable. However, within the blended treatment, we found that adherence to face-to-face mode was significantly higher than that of web mode, although the intended total treatment time for the blended treatment was fairly broadly adhered to. This supports the idea that in blended treatment, one mode of delivery can compensate for the weaknesses of the other. Older age was found to be a common predictor of adherence to the treatments. However, within the blended treatment, adherence to each mode was predicted by different characteristics: adherence to the face-to-face mode was associated with demographic

characteristics only, whereas adherence to the web mode of the blended treatment was also associated with several smoking-related and health-related characteristics. This may indicate that these characteristics should be taken into account when designing a blended treatment. However, the finding that only a small amount of the variance could be determined by the characteristics examined in this study suggests that provider-related health system factors and time-varying patient characteristics can also play an important role and should be explored in future research.

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Authorship

LS, MEP, MGJBK, and MGP identified the study questions, and designed the study and its measuring instruments. LS is the principal investigator and wrote the first draft of this manuscript. LS, MEP, MGJBK, MGP, RS, and SBA edited the manuscript. LS, MEP, MGJBK, MGP, and RS revised the manuscript. LS wrote the final version. All authors approved the final version of this manuscript for publication.

Ethics

In line with the Dutch Medical Research Ethics Committee (MREC) guidelines the study was approved by the accredited MREC Twente (P14-37/NL50944.044.14). Before initiation, the study was registered with the Dutch Trial Registration (NTR5113). All patients had to sign an informed consent form before they were randomized.

Conflict of interest

The authors declare that they have no competing interests.

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Effectiveness - Blended vs. Face-To-Face Treatment

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ABSTRACT

BACKGROUND

Traditional face-to-face interventions on the one hand and web-based interventions on the other hand are increasingly further developed into blended treatments. For smoking cessation, there is no evidence on the effectiveness of blended face-to-face and web-based treatment.

AIMS

The primary objective was to find out if a blended smoking cessation treatment results in non-inferior abstinence rates compared to a face-to-face treatment with identical ingredients. The secondary objective was to evaluate whether patients were more satisfied with the blended smoking cessation treatment compared to the face-to-face treatment.

DESIGN

A two-arm, parallel group, randomized controlled non-inferiority trial was conducted with 1:1 allocation using stratified randomization (nicotine dependency, internet skills, quitting strategy).

SETTING

The study was conducted in an outpatient smoking cessation clinic of a teaching hospital in the Netherlands.

PARTICIPANTS

Participants (n=344) were current smokers (at least one cigarette per day) who self-referred or were referred to the outpatient smoking cessation clinic by their General Practitioner (GP) or medical physician. They were over 18 years old, had access to the Internet and were able to read and write Dutch.

INTERVENTIONS

The study interventions to be compared were a blended face-to-face and web-based smoking cessation treatment (BSCT) and a face-to-face treatment (F2F). Except for the differences in mode of delivery (F2F-mode and Web-mode) both treatments had the same features.

MEASUREMENTS

For the primary objective (i.e. effectiveness), the main outcome was the proportion of biochemically (i.e. cotinine) validated abstinence from all combustible tobacco products at 3 months after start of the treatment. Additional outcomes were the proportions of CO-validated point prevalence abstinence, self-reported point prevalence abstinence, and self-reported continuous abstinence at 3 months (i.e. shortly after the expected quit date) and 6 months (i.e. end of treatment). BSCT was considered as non-inferior if it resulted in abstinence rates that were less than five percentage points lower than those of F2F. Additionally, Bayes Factors (BFs) were estimated based on the biochemically validated effectiveness outcomes (i.e. Cotinine; CO). For the secondary objective (i.e. satisfaction), outcomes related to patients' gained new insights into smoking (i.e. newly gained knowledge about smoking and additional knowledge about risk situations, risk feelings and risk thoughts), patients' thoughts of the results they had achieved during treatment, and what grades they would have given the counselors and the treatment.

FINDINGS

Three outcomes showed significantly (P<.001) lower abstinence rates in the BSCT group that were inferior to F2F based on the non-inferior margin of five percentage points: Cotinine-validated point prevalence abstinence at three months (difference 12.7; 95% CI 6.2-19.4), self-reported point prevalence abstinence at six months (difference 19.3%; 95% CI 11.5-27.0) and self-reported continuous abstinence at six months (difference 13.8%; 95% CI 6.8-20.8). For the remaining outcomes, the analysis showed inconclusive results for non-inferiority. Bayes factor calculation revealed very strong evidence (BF 0.02) of the inferiority of BSCT based on cotinine validated abstinence and anecdotal evidence of the non-inferiority of BSCT based on CO validated point prevalence abstinence. For patient's satisfaction similar positive evaluations were obtained for both treatments.

CONCLUSIONS

In this intermediate 6-month analysis of an RCT in which a blended smoking cessation treatment was compared with a comparable face-to-face treatment, the differences we found in terms of effectiveness, although some inconclusive, indicated an inferiority of the blended treatment, while patient satisfaction with both treatments was equally good.

INTRODUCTION

Killing more than eight million people each year, tobacco is a leading cause of death and illness (WHO, 2019). The risk of developing smoking-related illnesses can be significantly reduced by smoking cessation (WHO, 2020) and the majority of the smokers who are aware of the risks of smoking want to quit (WHO, 2019). Compared to quitting without professional support, smoking cessation treatment can more than double the success rates of quitting attempts (WHO, 2019); this ultimately results - for treatments comparable to those in this

study - in estimated point prevalence abstinence rates of 28.4% (CI 95% 21.3-35.5) for treatments with a total amount of contact time of 91-300 minutes, and of 24.7% (CI 95% 21.0-28.4) for treatments with more than eight person-to-person treatment sessions (both intention-to-treat; 6-months after quit date) (Fiore, Jaén, Baker, & al., 2008). Previous research in the clinic where the current study was conducted showed a 19% abstinence rate for a comparable treatment for the target group of COPD patients at 12-month follow-up (Christenhusz, 2006).

The past decades, a variety of effective interventions for smoking cessation have become available (Lancaster & Stead, 2017; Stead, Koilpillai, Fanshawe, & Lancaster, 2016), including more recently eHealth services such as web-based interventions (Civljak, Stead, Hartmann-Boyce, Sheikh, & Car, 2013; Taylor et al., 2017), or mobile-phone interventions (Whittaker et al., 2009; Whittaker, McRobbie, Bullen, Rodgers, & Gu, 2016). At present, traditional face-to-face interventions on the one hand and both web-based and mobile-phone interventions on the other hand are increasingly being further developed into blended treatments. This development goes along with the idea that blended treatment combines the “best of both worlds” (van der Vaart et al., 2014b; Wentzel, van der Vaart, Bohlmeijer, & van Gemert-Pijnen, 2016), as the strengths of one type of treatment should compensate for the weaknesses of the other (Barak, Hen, Boniel-Nissim, & Shapira, 2008; Erbe, Eichert, Riper, & Ebert, 2017; Kemmeren et al., 2016; Postel, Witting, & Gemert-Pijnen, 2013; Lutz Siemer et al., 2019; L. Siemer, Ben Allouch, et al., 2020; van der Vaart et al., 2014a; Wentzel et al., 2016). For example, personal attention by a professional in the case of face-to-face treatment could compensate for the lack of personal contact in the case of web-based treatment. In turn, one of the main features of web-based treatment is the possibility of being available anytime and anywhere, which could bridge the intervals between sessions in face-to-face treatment.

A systematic review (Erbe et al., 2017) of randomized controlled trials (RCT) on blended face-to-face and web-based interventions suggests that compared with stand-alone face-to-face therapy, blended therapy may save clinician time, lead to lower dropout rates and greater abstinence rates of patients with substance abuse. The authors concluded that for common mental health disorders, blended interventions are feasible and can be more effective compared with no treatment controls, but more RCTs on effectiveness of blended treatments compared with nonblended treatments are necessary. The evidence for patient satisfaction with blended treatment was even scarcer, as we found only one study on this. This rather small-scale (n=7) evaluation of cognitive behavioral treatment for major depression (Kooistra et al., 2016) showed that the patients were predominantly satisfied.

Although promising, the evidence available for blended addiction treatment is still emerging, and limited to substances like alcohol (Blankers, 2020), cocaine, marijuana

(Carroll et al., 2008), or opioids (Christensen et al., 2014). For smoking cessation, to the best of our knowledge, there are no published research results on the effectiveness and patient satisfaction with blended treatments, either as RCT or in any other form. Therefore, in this study we present the first findings of an RCT comparing a blended treatment with traditional face-to-face treatment similar in content and intensity. With this intermediate six-months analysis we addressed two of the objectives laid out in the study protocol of the LiveSmokefree-Study (L. Siemer et al., 2016):

(1) Primary objective was to find out if a blended smoking cessation treatment results in non-inferior abstinence rates compared to a face-to-face treatment with identical ingredients. The rationale for choosing a non-inferiority design was that we expected secondary benefits for BSCT, such as lower costs, lower dropouts and higher patient satisfaction, even if BSCT only led to comparable abstinence rates.
(2) The secondary objective was to evaluate whether patients were more satisfied with the blended smoking cessation treatment compared to the face-to-face treatment. The rationale for the expectation that BSCT would lead to higher patient satisfaction was the assumption that BSCT would be less time-consuming and costly (fewer hospital visits means less travel efforts) and more user-friendly (due to the web offerings) for patients.

METHODS

DESIGN

This study showed the intermediate six-months analysis of an unblinded two-arm, parallel group, randomized controlled non-inferiority trial with 1:1 allocation using stratified randomization (nicotine dependency, internet skills, quitting strategy).

SETTING

The study was conducted at the outpatient smoking cessation clinic (Dutch: Stoppen met Roken Poli (SRP)) of Medical Spectrum Twente hospital (MST) in Enschede, The Netherlands. Enschede is a municipality and city in the east of the Netherlands with a population of 150,000 inhabitants. The estimated daily smoking prevalence in Enschede is 17.2% in 2017, which is about the same as the average (17.4%) in the Netherlands, which is one of the least smoking countries in Europe (Van Laar & van Gestel, 2018).

PARTICIPANTS

Recruitment took place between March 2015 and March 2019. The participants self-referred to the treatment or were referred to the clinic by their GP or medical physician. A patient information letter that outlined the burden of participation was handed out to all patients and the patients were called by members of the research department to check for eligibility.

Eligible were current smokers (at least one cigarette per day) who were over 18 years old, had access to the Internet (email, websites) and were able to read and write Dutch. Eligible patients attended an intake interview and signed a consent form before filling out the baseline questionnaire and being randomized.

INTERVENTIONS

The study interventions to be compared were a blended face-to-face and web-based smoking cessation treatment (BSCT) and a face-to-face treatment (F2F). Except for the differences in mode of delivery (i.e. F2F-mode and Web-mode) both treatments had the same features:

1. High-intensity treatment that comprised 10 sessions (20 minutes contact time each, except for the first, which lasts 50 minutes) within a six-month period with an expected quit date after about three months.
2. Delivered by health care professionals in an outpatient cessation clinic.
3. Concordant with the Dutch Guideline Tobacco Addiction (Partnership Stop met Roken, 2009a), fulfilling the requirements of the Dutch care module for smoking cessation (Partnership Stop met Roken, 2009b).
4. Executed by counselors, registered in the Dutch quality register of qualified smoking cessation counselors.
5. Supporting three quitting strategies – at start patients choose to (1) stop at once, (2) change gradually by increasing the number of daily activities that are done smoke-free, or (3) decrease smoking at regular intervals (scheduled smoking reduction e.g. 100%->75%, 75%->50%). The chosen quitting strategy did not influence the course of the treatment in general. The order, pace, duration, and intensity were the same for all strategies.

Both BSCT and F2F covered 52 behavior change techniques (using Michie et al.'s "BCT taxonomy v1: 93 hierarchically-clustered techniques" (Michie et al., 2013)) as shown in Table 18.

TABLE 18. Behavior change techniques included in BSCT and F2F

Grouping	Behavior change technique
1. Goals and planning	1.1 Goal setting (behavior)
	1.2 Problem solving
	1.3 Goal setting (outcome)
	1.4 Action planning
	1.5 Review behavior goal(s)
	1.6 Discrepancy between current behavior and goal
	1.8 Behavioral contract
	1.9 Commitment
2. Feedback and monitoring	2.3 Self-monitoring of behavior
	2.4 Self-monitoring of outcome(s) of behavior
	2.6 Biofeedback
	2.7 Feedback on outcome(s) of behavior
3. Social support	3.1 Social support (unspecified)
4. Shaping knowledge	4.2 Information about antecedents
	4.3 Re-attribution
5. Natural consequences	5.1 Information about health consequence
	5.2 Salience of consequences
	5.3 Information about social and environmental consequences
	5.4 Monitoring of emotional consequences
	5.5 Anticipated regret
	5.6 Information about emotional consequences
6. Comparison of behavior	6.2 Social comparison
	6.3 Information about others' approval
7. Associations	7.4 Remove access to the reward
8. Repetition and substitution	8.1 Behavioral practice/ rehearsal
	8.2 Behavior substitution
	8.3 Habit formation
	8.4 Habit reversal
	8.6 Generalization of a target behavior
	8.7 Graded tasks
9. Comparison of outcomes	9.1 Credible source
	9.2 Pros and cons
	9.3 Comparative imagining of future outcomes
10. Reward and threat	10.7 Self-incentive
	10.9 Self-reward
11. Regulation	11.1 Pharmacological support
	11.2 Reduce negative emotions
12. Antecedents	12.1 Restructuring the physical environment
	12.2 Restructuring the social environment
	12.3 Avoidance/reducing exposure to cues for the behavior
	12.4 Distraction
13. Identity	13.1 Identification of self as role model
	13.2 Framing/reframing
	13.5 Identity associated with changed behavior
14. Scheduled consequences	14.4 Reward approximation
	14.5 Rewarding completion
	14.6 Situation-specific reward
	14.7 Reward incompatible behavior
	14.8 Reward alternative behavior
15. Self-belief	15.1 Verbal persuasion about capability
	15.3 Focus on past success
16. Covert learning	16.3 Vicarious consequences

F2F consisted of ten F2F-mode sessions delivered at the outpatient smoking cessation clinic. BSCT consisted of five F2F-mode sessions at the outpatient clinic and five Web-mode session delivered via the online treatment platform www.rokendebaas.nl (which translates loosely as “smoking manager”). During the RCT, the software had to be revised once, as the European General Data Protection Regulation became enforceable from 25 May 2018, which changed the appearance and handling, but not the content of the interventions.

Both F2F and BSCT consisted of both counselor-dependent and counselor-independent components. The counselor-dependent web-based components of BSCT were interactive and relied on (asynchronous) communication (email, messaging) between counselor and patient. The counselor-independent components such as psycho-educational content or the smoking diary were used by the patients on their own and in their own time. In F2F these components were provided in a paper manual that clients took home. In BSCT, these components were accessible online. As such, both treatments were equivalent with regard to both content and intensity. An additional benefit of BSCT, though, was that the content of previous counselor-dependent components remained accessible as email and messaging correspondence saved online.

The characteristic feature of BSCT is a 50-50 balance for F2F-mode and Web-mode sessions – the focus of the treatment was not supposed to be on the F2F-mode nor on the Web-mode; in addition, there is a constantly alternating and interacting use of F2F-mode and Web-mode. Table 19 shows the order, timing, main features, duration, and modes of delivery of the treatment sessions in F2F and BSCT. Although a 50-50 distribution was planned for BSCT with regard to the number of sessions, there was an uneven distribution for the duration of treatment because the first session (50 min F2F-mode) was longer than the remaining sessions (20 min F2F-mode or 20 min Web-mode): BSCT patients thus spent 130 min in F2F-mode and 100 min in Web-mode.

TABLE 19. Characteristics of the treatment sessions in F2F and BSCT according to treatment protocol

Session	Week	Main features	Duration (min)	Mode of delivery	
				BSCT	F2F
			230	130 min F2F-mode[a] 100 min Web-mode[b]	230 min F2F-mode
1	1	Goal setting; Prompt smoking diary; Measure CO[c]	50	F2F-mode	F2F-mode
2	3	Measures for self-control	20	Web-mode	F2F-mode
3	5	Dealing with withdrawal	20	F2F-mode	F2F-mode
4	7	Breaking habits	20	Web-mode	F2F-mode
5	9	Dealing with triggers	20	F2F-mode	F2F-mode
6	11	Food for thought	20	Web-mode	F2F-mode

TABLE 19 continued.

Session	Week	Main features	Duration (min)	Mode of delivery	
				BSCT	F2F
			230	130 min F2F-mode[a] 100 min Web-mode[b]	230 min F2F-mode
7	14	Think differently; Measure CO, Measure Cotinine[d]	20	F2F-mode	F2F-mode
8	18	Do differently	20	Web-mode	F2F-mode
9	22	Action plan; Measure CO	20	F2F-mode	F2F-mode
10	26	Closure	20	Web-mode	F2F-mode

[a]F2F-mode, face-to-face treatment session of the blended smoking cessation treatment
[b]Web-mode, web-based sessions of the blended smoking cessation treatment
[c]CO, Carbon monoxide measurement
[d]Cotinine measurement was only done in patients who reported quitting either in the three-months follow-up questionnaire or during treatment to the counselor

More information about both treatments can also be found in the study protocol of the RCT (L. Siemer et al., 2016) and in the description of the user experiences of BSCT (L. Siemer, Ben Allouch, et al., 2020). The treatment fidelity of the counselors was not recorded. The adherence to the treatments was described elsewhere (L. Siemer et al., 2018; L. Siemer, Brusse-Keizer, et al., 2020), but, in brief, levels of adherence were comparable for BSCT and F2F. To provide an impression of the look and feel of the Web interventions of BSCT, Multimedia Appendix 1 shows screenshots of the Web sessions of BSCT.

OUTCOMES

For the primary objective (i.e. effectiveness) of the intermediate analysis, the primary outcome for the intention-to-treat (ITT) analysis of the treatments’ effectiveness in smoking cessation was the proportions of biochemically (i.e. cotinine) validated point prevalence abstinence from all combustible tobacco products (cigarettes, bags, cigars, pipes) at three months after start of the treatment. Additional outcomes were the proportions of CO-validated point prevalence abstinence, self-reported point prevalence abstinence, and self-reported continuous abstinence at three months (i.e. shortly after the expected quit date) and six months (i.e. end of treatment). Applying the non-inferiority margin justified in the protocol article (L. Siemer et al., 2016), BSCT was considered as non-inferior if it resulted in abstinence rates that were less than five percentage points lower than those of F2F.

For the secondary objective (i.e. satisfaction), outcomes related to the intermediate evaluation of treatments at three and six months after start of the treatment.

MEASUREMENTS

Effectiveness

Cotinine-validated and CO-validated abstinence were used to measure biochemically

validated point prevalence abstinence (N. L. Benowitz et al., 2019; Neal L Benowitz et al., 2002; Hughes et al., 2003).

Cotinine measurement was performed at around three months follow-up (i.e., shortly after the expected quit day; week 14, see Table 2) only in patients who reported quitting either in the three-months follow-up questionnaire or during treatment to the counselor. A 0,5–1 ml salivary sample was collected by means of a Salivette (Sarstedt AG & Co., Nümbrecht, Germany). Under supervision, patients chew on a cotton swab for 1min to stimulate the saliva flow rate. All saliva specimens were frozen until assayed and transported to the laboratory for the determination of the cotinine level using a gas chromatography technique. Abstinence was defined as having salivary cotinine levels <20 ng/ml (Jarvis, Fidler, Mindell, Feyerabend, & West, 2008).

CO-measurement was done in all patients (independent of reporting quitting) at three months and at the last face-to-face treatment session at the hospital (BSCT group: last face-to-face treatment session was at five months after start of the treatment (week 22); F2F group: six months after start of the treatment (week 26), see Table 2). A breath CO level of 5 ppm was taken as the cut-off between smokers and nonsmokers (5 ppm or higher = smoker, less than 5 ppm = non-smoker) (Cropsey et al., 2014). Breath CO monitoring was performed using a piCo Smokerlyzer (Bedfont Instruments: Kent, UK), a portable CO monitor.

In addition, self-reported point prevalence abstinence and self-reported continuous abstinence were measured at three and six months after treatment initiation. The measurement tool was a standardized questionnaire for Dutch tobacco research (Mudde, 2006), which both BSCT and F2F patients completed online. Self-reported point prevalence abstinence was assessed by asking patients whether they had smoked one or more cigarettes (bags, cigars, pipe) in the last 7 days; self-reported continuous abstinence was assessed by asking whether they had smoked since the current stop.

Satisfaction

Three months after the start of treatment, the participants of both groups were asked to what extent they had gained new insights into smoking (i.e. newly gained knowledge about smoking and additional knowledge about risk situations, risk feelings and risk thoughts). Six months after the start of treatment, the participants were asked what they thought of the results they had achieved during the treatment, and what grades they would have given the counselors and the treatment. Standardized questionnaires for Dutch tobacco research (Mudde, 2006), completed online, were used as measuring instruments after three and six months. The exact wording of the questions and the scaling of the answers are given in Table 22.

SAMPLE SIZE

This was an intermediate analysis at six months after start of the treatment. The sample size, however, was calculated for the analysis at 15 months after start of the treatment. For the 15-months analysis a sample of 344 participant had been calculated, assuming a long-term abstinence rate of 10% with F2F (Christenhusz, 2006; Christenhusz , Prenger, Pieterse, Seydel, & van der Palen, 2012; Fiore et al., 2008), and – based on its expected benefits - 15% with BSCT. If BSCT would lead to an abstinence rate not lower than 5% it would be considered as non-inferior compared to F2F. Therefore, with a power of 80% and α of 0,025 172 patients per group were needed for this RCT (calculated with PASS).

RANDOMIZATION

Patients giving written consent were allocated randomly to either BSCT or F2F using computerized randomization (QMinim Online Minimization). Randomization was performed on the individual level (allocation ratio 1:1). The minimization was stratified according to: (1) level of internet skills (van Deursen, Courtois, & van Dijk, 2014); (2) level of nicotine dependence (Mudde, 2006); and (3) the quitting strategy favored by the patient (stop at once, gradual change, scheduled reduced smoking; for details see above the description of the study intervention). The data used for the minimization was collected using the baseline questionnaire, which was filled in online by the patient after giving consent.

BLINDING

Due to the nature of the treatment conditions, it was self-evidently impossible to blind the staff and patients that were involved.

STATISTICAL METHODS

For both the BSCT group and the F2F group, the patients' demographic, smoking-related, and health-related characteristics at baseline were reported as means with standard deviations (SDs) for normally distributed continuous variables and as medians with interquartile ranges (IQRs) for not-normally distributed continuous variables. Categorical variables were reported as numbers with corresponding percentages. To identify between group differences, independent T tests or Mann-Whitney-U tests were performed as appropriate for continuous variables; Pearson chi-square or Fisher's exact test were performed for categorical variables. This procedure was applied equally to the analysis of the satisfaction data three and six months after the start of treatment.

Since this was an ITT analysis, participants with missing data on smoking status were considered still smokers. The absolute and proportional abstinence rates by treatment group were reported. The non-inferiority was analyzed by calculating the difference and the 95% confidence interval of the observed difference in the abstinence rates and by

comparing that to the previously defined non-inferiority margin of five percentage points. Furthermore, the non-inferiority analysis was illustrated in a forest chart.

Additionally, Bayes Factors (BFs) (Beard, Dienes, Muirhead, & West, 2016) were estimated based on the ITT analysis of the biochemically validated effectiveness outcomes (i.e. Cotinine; CO). The BF for non-inferiority allows for explicit quantification of evidence favoring the non-inferiority hypothesis versus the inferiority hypothesis expressed as a likelihood ratio (van Ravenzwaaij, Monden, Tendeiro, & Ioannidis, 2019). BFs >1|>3|>10|>30 were considered to provide anecdotal|moderate|strong|very strong support for non-inferiority, whereas BFs <1|<0.33|<0.10|<0.03 as anecdotal|moderate|strong|very strong evidence for inferiority (Lee & Wagenmakers, 2014).

All analyses were performed using the Statistical Package for Social Sciences (SPSS), version 26 (IBM, Armonk, NY, USA), except for the calculation of the confidence intervals of the difference between abstinence rates, for which we used Vassarstat's web tool for "The Confidence Interval For The Difference Between Two Independent Proportions" at http://vassarstats.net/prop2_ind.html; and the BF calculation, for which we used "baymedr: An R Package for the Calculation of Bayes Factors for Equivalence, Non-Inferiority, and Superiority Designs" (Linde & van Ravenzwaaij, 2019).

RESULTS

PARTICIPANT FLOW

Figure 6 shows the flow of participants through the study. 344 patients were eligible for the study, gave written consent and were randomized (BSCT=177; F2F=177). 167 (94%) patients of the BSCT group and 177 (100%) of the F2F group started treatment (i.e. they had at least one session). Before start of the treatment, 151 (85%) patients of the BSCT group and 175 (99%) patients of the F2F group filled in the baseline questionnaire. Three months after starting treatment (i.e. shortly after the expected quit date), 14 (8%) of the 22 patients of the BSCT group that self-reported quitting were available for cotinine measurement, 68 (38%) patients were available for CO measurement, and 51 (29%) completed the follow-up questionnaire. In the F2F group, 47 (27%) of the 47 patients that reported quitting were available for cotinine measurement, 77 (44%) were available for CO measurement, and 94 (53%) patients completed the 3-month follow-up questionnaire. 53 (30%) patients of the BSCT group were available for the 5-months CO measurement and 37 (21%) completed the 6-months follow-up questionnaire. Within the F2F group, 60 (35%) patients were available for the 6-months CO measurement and 89 (50%) filled in the 6-months follow-up questionnaire.

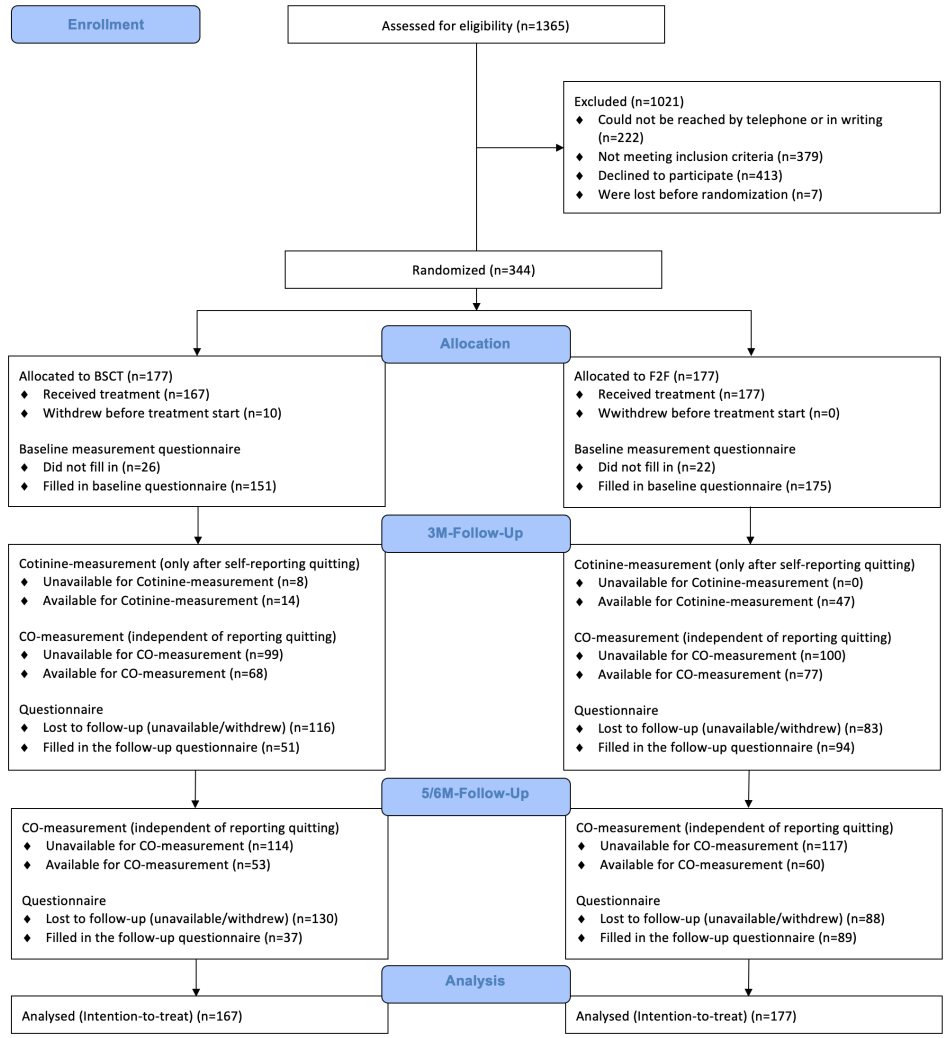

FIGURE 6. Flow of participants through the study. Withdrawals are non-cumulative. some participants who were unavailable at 3-months follow-up were available again at 5/6-months follow-up

BASELINE CHARACTERISTICS

Table 20 shows that no significant differences were found for participants in both groups, including demographic, smoking-related, and health-related characteristics.

TABLE 20. Patients' characteristics of both the BSCT group and the F2F group

Characteristic	BSCT (N=151)	F2F (N=175)
Demographic		
Sex		
Female (%)	77 (50.7)	87 (49.7)
Male (%)	75 (49.3)	88 (50.3)
Nationality		
Dutch (%)	147 (96.7)	173 (98.9)
Other (%)	5 (3.3)	2 (1.1)
Cultural background		
Dutch (%)	137 (90.1)	161 (92.0)
Other (%)	15 (9.9)	14 (8.0)
Age; years, mean (SD)	47.5 (12.4)	46.4 (13.2)
Marital status		
With partner (%)	99 (65.6)	107 (61.1)
Alone (%)	52 (34.4)	68 (38.9)
Housing situation		
With children (%)	63 (41.5)	73 (42.4)
Without children (%)	89 (58.5)	99 (57.6)
Education		
VET or higher (%)	96 (63.2)	109 (63.7)
Lower than VET (%)	56 (36.8)	62 (36.2)
Main income		
Wage or own (%) company (%)	79 (52.0)	89 (50.9)
Income support (%)	73 (48.0)	86 (49.1)
Main day activity		
Paid work (%)	77 (50.7)	85 (48.6)
Other (%)	75 (49.3)	90 (51.4)
Internet skills; mean (SD)	38.4 (6.5)	39.4 (5.8)
Smoking-related		
Quitting strategy		
Stop at once (%)	68 (40.7)	72 (40.9)
Change gradually (%)	44 (26.3)	44 (25.0)
Scheduled reduction (%)	55 (32.9)	60 (34.1)
Reason to start treatment		
Intrinsic (%)	104 (68.4)	117 (66.9)
Extrinsic (%)	48 (31.6)	58 (33.1)
Nicotine dependency (Fagerström); mean (SD)	5.3 (2.1)	5.2 (2.1)
Negative attitude towards quitting; mean (SD)	-5.5 (3.1)	-5.1 (2.9)
Positive attitude towards quitting; median (IQR)	10 (8-11)	10 (9-11)
Self-efficacy; mean (SD)	-.2 (5.2)	-.4 (4.9)
Readiness to quit; median (IQR)	2 (1-3)	2 (1-3)
Earlier quit attempts (%)	128 (84.8)	154 (88.0)
Social support; median (IQR)	4 (3-4)	4 (3-5)
Social modelling; median (IQR)	3 (1-6)	3 (1-5)
Use of alcohol; median (IQR)	2 (1-3)	2 (1-3)
Use of (recreational) drugs (%)	11 (7.3)	15 (8.6)

TABLE 20 continued.

Characteristic	BSCT (N=151)	F2F (N=175)
Health-related		
Use of medication in general (%)	102 (67.5)	130 (74.3)
Use of medication for addiction treatment (%)	0 (0)	0 (0)
Use of medication for psychiatric treatment (%)	30 (19.9)	26 (16.4)
Use of medication for physical treatment (%)	78 (51.7)	93 (58.5)
Use of other medication (%)	25 (16.6)	31 (19.5)
Health complaints (MAP HSS); mean (SD)	12.6 (6.2)	12.6 (6.6)
Smoking related complaints; mean (SD)	21.0 (13.6)	20.8 (9.2)
Health and smoking related complaints; mean (SD)	33.6 (13.6)	33.4 (14.2)
Depression; median (IQR)	4 (0-10)	4 (2-12)
Anxiety; median (IQR)	4 (2-8)	6 (2-10)
Stress; median (IQR)	8 (4-16)	10 (4-16)
DASS; median (IQR)	18 (8-32)	20 (8-36)
EQ-5D-3L; median (IQR)	.8 (.7-1.0)	.8 (.7-.9)
EQ VAS; mean (SD)	65.5 (18.7)	64.6 (18.7)

%, percentage; IQR, inter quartile range; SD, standard deviation;
VET, vocational education and training; Internet skills (range 10 - 60; higher number indicates better skills); Nicotine dependency (Fagerstroem) (range 0 - 10; higher numbers indicate higher nicotine dependency); Negative attitude towards quitting (range -12 - 0; lower numbers indicate a more negative attitude towards quitting smoking); Positive attitude towards quitting (range 0 - 12; higher numbers indicate a more positive attitude towards quitting smoking); Self-efficacy (range -12 - 12; higher numbers indicate higher self-efficacy related to smoking cessation); Readiness to quit (range 0 – 4: higher numbers indicate higher readiness to quit); Social support (range 0 – 5; higher numbers indicate more social support in smoking cessation); Social modelling (range 0 – 8; higher numbers indicate more smokers in the social environment); Use of alcohol (range 0 -4; 0=Never, 1=1 time per month, 2=2-4 times a month, 3=2-3 times a week, 4=4 times or more per week); Health complaints (MAP HSS), Maudsley Addiction Profile Health Symptoms Scale (range 0 – 40; higher numbers indicate poorer health status); Smoking related complaints (range 0 - 64; higher numbers indicate more smoking related complaints); Health and smoking related complaints (range 0 – 104; higher numbers indicate poorer health status and more smoking related complaints); Depression/Anxiety/Stress (range 0 – 42; higher number indicate a higher level of depression/anxiety/stress); DASS, sum score of Depression/Anxiety/Stress (range 0 – 126; higher numbers indicate a more negative emotional status); EQ-5D-3L, societal-based quantification of the patients' health status (range 0 – 1; higher numbers indicate better health status); EQ VAS, visual analogue scale for quality of life (range 0 – 100, higher numbers indicate better state of health)

EFFECTIVENESS

Table 21 shows the results for effectiveness measurements three and five/six months after start of treatment. The cotinine-validated point prevalence abstinence three months after treatment initiation (i.e. shortly after the expected stop day) shows a significantly lower and inferior abstinence rate in the BSCT group (4.8%) compared to the F2F group (17.5%) (difference of 12.7 (95% CI 6.2-19.4); P<.001). Furthermore we observed a significant lower and inferior self-reported point prevalence abstinence at five/six months in the BSCT group (7.8%) vs F2F (27.1%) (difference of 19.3 (95% CI 11.5-27.0); P<.001) and a significantly lower and inferior self-reported continuous abstinence rate in BSCT (6.0%) vs F2F (19.8%); (difference of 13.8 (95% CI 6.8-20.8); P<.001) at five/six months.

TABLE 21. Treatment effects on number of participants at 3 and 5/6 months after start of treatment

Outcome	BSCT n (%)	F2F n (%)	Difference (95% CI)
3 months			
Cotinine-validated point prevalence abstinence	8/167 (4.8%)	31/177 (17.5%)	12.7 (6.2-19.4)
CO-validated point prevalence abstinence	43/167 (25.7%)	50/177 (28.2%)	2.5 (-6.9-11.8)
Self-reported point prevalence abstinence[a]	22/167 (13.2%)	35/177 (19.8%)	6.6 (-1.3-14.4)
Self-reported continuous abstinence[b]	19/167 (11.4%)	30/177 (16.9%)	5.6 (-1.9-13.0)
5/6 months			
CO-validated point prevalence abstinence	23/167 (13.8%)	31/177 (17.5%)	3.7 (-4.0-11.4)
Self-reported point prevalence abstinence[a]	13/167 (7.8%)	48/177 (27.1%)	19.3 (11.5-27.0)
Self-reported continuous abstinence[b]	10/167 (6.0%)	35/167 (19.8%)	13.8 (6.8-20.8)

[a] Answer "No" to the questionnaire question "Have you smoked one or more cigarettes (bags, cigars, pipe) in the last 7 days?"
[b] Answer „No" to the questionnaire question "Have you smoked since the stop?"

In Figure 7 the 95% confidence intervals of the differences between BSCT and F2F for all abstinence outcome measure are presented with applying the five-percentage-points non-inferiority margin. As previously mentioned, the analysis showed inferiority of BSCT with cotinine-validated point prevalence abstinence at three months, self-reported point prevalence abstinence at six months and self-reported continuous abstinence at six months. For the remaining outcomes, the analysis showed inconclusive results.

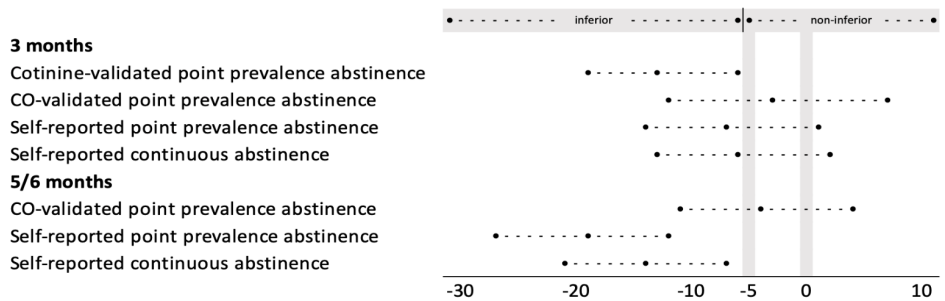

FIGURE 7. Forest plot of the risk differences between BSCT (CI 95%) and F2F

The Bayes factor calculation based on the biochemically validated outcomes revealed:

Cotinine-validated point prevalence abstinence (three months):	BF 0.02
CO-validated point prevalence abstinence (three months):	BF 2.61
CO-validated point prevalence abstinence (five/six months):	BF 1.97

When applying the above-mentioned BF interpretation (Lee & Wagenmakers, 2014), there is, on the one hand, very strong evidence of the inferiority of BSCT based on cotinine validated point prevalence abstinence, while, on the other hand, there is only anecdotal evidence of the non-inferiority of BSCT based on CO validated point prevalence abstinence.

SATISFACTION

Table 22 shows that similar positive evaluations were obtained for both treatments. The participants in both groups stated that they had learned "quite a bit" (mean 2.8-2.9; see Table 22 footer) with regard to risk situations, feelings of risk, and risk thoughts, and that they had gained "a little" (mean 2.4; see Table 22 footer) new knowledge about smoking. The participants in both groups also thought that they had achieved "good" (median 2; see Table 22 footer) results with the treatment and graded both the treatment (mean 7.7-7.9) and the counselors (mean 8.3-8.5) as "good".

TABLE 22. Patient satisfaction with the treatments and the counselors

Outcome	BSCT	F2F	P
3 months			
Have you gained more insight into your risk situations?[a]	2.8 (N=51; SD .7)	2.8 (N=93; SD .8)	.99
Have you gained more insight into your feelings of risk?[a]	2.8 (N=51; SD .7)	2.9 (N=93; SD .7)	.96
Have you gained more insight into your risk thoughts?[a]	2.9 (N=51; SD .7)	2.8 (N=93; SD .7)	.66
Have you gained new knowledge about smoking?[a]	2.4 (N=51; SD .9)	2.4 (N=93; SD .9)	.99
6 months			
What do you think of the results you have achieved with this treatment?[b]	2 (N=34; IQR 2-3)	2 (N=84; IQR 1-3)	.52
What grade do you give the counsellor?[c]	8.3 (N=34; SD 1.1)	8.5 (N=83; SD 1.1)	.28
What grade do you give this treatment?[c]	7.7 (N=34; SD 1.2)	7.9 (N=83; SD 1.5)	.44

[a]Range 1-4 (1="not at all"; 2="a little"; 3="quite a bit"; 4="very much")
[b]Range 1-5 (1="very good"; 2="good"; 3="moderate"; 4="not good"; 5="bad")
[c]Range 1-10 (Note: In the Netherlands, most institutions grade exams, papers and thesis on a scale from 1 (very poor) to 10 (outstanding). The mark 9 (very good) is seldom awarded (in only 2.7% of cases), and the highest pass mark 10 is extremely rare (in only 0.1%) of cases as this implies perfection. (Nuffic))

DISCUSSION

MAIN FINDINGS

This paper presents the intermediate 6six-months results of the – to the best of our knowledge – first RCT comparing the effectiveness of a blended face-to-face and web-based smoking cessation treatment (BSCT) to a face-to-face only treatment (F2F) with similar ingredients and similar intensity. Contrary to our own expectations, the abstinence rates of BSCT were lower than those of F2F. For the primary outcome (i.e. cotinine validated point prevalence abstinence), the application of the five-percentage points non-inferiority margin and the resulting calculation of the Bayes Factor indicated the inferiority of BSCT. On the one hand, these results should be considered with great caution, as there was only a very low response rate for cotinine validated point prevalence abstinence (see limitations below). On the other hand, we also found inferiority of BSCT in two of the secondary outcomes (self-reported point prevalence abstinence and self-reported continuous abstinence at six months), while the remaining outcomes were inconclusive. For the comparative assessment of patients' satisfaction there was no evidence of differences: Both BSCT and F2F were similarly rated "good".

Since we found BSCT inferior to F2F we cannot confirm the higher abstinence rates reported in the literature (Erbe et al., 2017) for blended treatments compared to face-to-face treatment. The reasons for the inferiority of BSCT still need further clarification. As both patients' demographic, smoking-related, and health-related characteristics and patients' reports of satisfaction with new smoking insights, results achieved and consultant and treatment scores were comparable in both treatments, these factors did not seem to play a role in this context. This also applies to adherence, since, as we found in previous analyses (L. Siemer, Brusse-Keizer, et al., 2020), adherence was also comparable for both groups. However, we know from qualitative analyses within the framework of this RCT that factors such as persuasiveness and hedonism may have played a role (L. Siemer, Ben Allouch, et al., 2020) and we expect that the 50-50 mix chosen in this study was too restrictive for blended treatment in practice (L. Siemer, Brusse-Keizer, et al., 2020), thus allowing too little tailoring to individual patient needs. Furthermore, even if this cannot yet be supported by systematic observations and analyses, we think that provider factors at the micro-level (e.g. the treatment fidelity of counselors, therapist drift) and at the meso-level (e.g. the organization's preexisting knowledge and skills base or its leadership and vision) should be considered more closely. As an example, in the case of the development of BSCT, half of the interventions of the F2F treatment established in the outpatient smoking cessation clinic were replaced by online tools of a web platform unknown to the clinic and the counsellors. Whether the starting point of the development of a blended treatment is face-to-face or web, or whether it really starts from scratch, may have an impact. Another example: Towards the end of the RCT, the web platform had to be revised due to legal changes, which caused technical problems and teething troubles on the one hand, but on the other hand also burdened patients and counsellors with new adaptation efforts. As only a few patients were affected by this change towards the end of the RCT, these had no relevant influence on the results of this study, but the noticeable uneasiness of such a change shows the relevance of such processes. Further practical observations and theoretical modelling should address how differences in effectiveness can be explained, for example, in line with the model for innovation in health services by Greenhalgh et al. (Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou, 2004) by questions such as "What explains the success of a blended treatment in one context and the failure of a comparable blended treatment in another context?"

Even though it was not the focus of this analysis, it was noticeable that both treatments mostly showed lower abstinence rates than reported in the literature for comparable treatments (i.e. point prevalence abstinence rates of 28.4% for treatments with a total amount of contact time of 91-300 minutes six-months after quit date (Fiore et al., 2008)). Depending on the outcome, the abstinence rates of BSCT and F2F ranged from 4.8% (BSCT; cotinine-validated point prevalence abstinence) to 28.2% (F2F, CO-validated point prevalence abstinence) shortly after quit-date (i.e. 3-months after start of the treatment), and 6.0% (BSCT; self-reported continuous abstinence) to 27.1% (F2F; Self-reported point prevalence abstinence) 3-months after quitting (i.e. six-months after start of the treatment). It should also be noted that our follow-up measurements took place earlier (i.e. shortly after the expected quit day and three months after the expected quit day) than in the comparative values taken from the literature (six months after the quit day). Since the abstinence rates are lower for longer follow-up measurements due to increased relapse rates, one can assume even lower abstinence rates for BSCT and F2F, if these would also have been measured six months after the quit day. A possible explanation for the lower abstinence rates compared to other studies could be the group of patients studied (i.e. patients in an outpatient smoking cessation clinic in a hospital context). A further analysis should investigate whether the sample differs from the general population in terms of known effectiveness predictors (Holm et al., 2017), such as, in this context, age, socioeconomic status, alcohol and drug use, health status, nicotine dependence, motivation to quit or family status. However, a previous study (Christenhusz, 2006) in this clinic with a comparable treatment for the specific target group of COPD patients showed slightly higher abstinence rates (19%) compared to F2F (17.5%) and a much higher abstinence rate compared to BSCT (4.8%) at 12-month follow-up. That said, we also found another unexpected result noteworthy that steered the thinking in another direction. In the three-month measurement the CO-validated point prevalence abstinence (BSCT 25.7%; F2F 28.2%) is higher than the self-reported point prevalence abstinence (BSCT 13.2%; F2F19.8%). This is very unusual and indicates a confounding due to lack of data, which in turn raises the question of which abstinence rates are most valid.

Even if blended treatment appears promising and results from today's digitalization of the lifestyle of patients and healthcare professionals (van der Vaart et al., 2014b; Wentzel et al., 2016), not every realization of blended treatment is automatically an improvement. If the inferiority of BSCT as suggested in this analysis will be confirmed in the final analysis of the RCT, the current realization of BSCT will have to be reconsidered. And future approaches should be carefully elaborated with regard to the different aspects of innovation in health care and their many interactions such as for example the different possible formats of blended treatments (e.g. integrated tools such as web platforms, e-mails, SMS/messenger, apps; mainly web-based vs. mainly face-to-face; integrated vs. sequential; simple vs. complex; protocolled vs. tailor-made), the target groups to be addressed (i.e. striving for optimal matching between patient and treatment), and the professionals who carry out the treatment (e.g. background more in F2F or Web-based treatment). This can be supported by an eHealth development model such as the CeHRes Roadmap (van Gemert-Pijnen et al., 2011), the model for innovation in healthcare by Greenhalgh et al. (Greenhalgh et al., 2004), or quite practically by the "Fit for Blended Care" instrument (Wentzel et al., 2016), which is intended to support therapists and patients in deciding whether and how blended care can be established.

LIMITATIONS

A major limitation of this intermediate study was that unfortunately only a very small number of cotinine measurements were available. The small amount of cotinine measures had a major impact on the ITT analysis. Yet the inferiority of BSCT was also supported by the fact that two of the four self-reported measurements also showed inferiority while the remaining measurements were inconclusive.

With regard to the CO measurements, an additional limitation was that for reasons of practicability (i.e. last F2F meeting in the hospital) the second measurements in the BSCT group were taken five months after the start of treatment and those in the F2F group after six months. Under the assumption that the abstinence rates should have been lower due to increasing relapses at later measurement dates, this would have resulted in an advantage for BSCT, which would have led to slightly higher abstinence rates for BSCT.

A further limitation is that, as is often the case in clinical studies (G. Waller, 2009), we have not recorded the treatment fidelity and thus deviations from the treatment protocol, for example due to the therapist drift widely present in cognitive behavioral therapy (Glenn Waller & Turner, 2016), could have biased our findings. Although we cannot rely on systematic observations, we considered that the implementation and adoption of the innovative BSCT may have had a negative impact on the effectiveness of the BSCT compared to the usual F2F treatment. Again, based on our data on adherence from previous papers (L. Siemer et al., 2018; L. Siemer, Brusse-Keizer, et al., 2020) and the findings on satisfaction in this paper, we found no indication of a fidelity issue.

For the generalization of the results it should be noted that this analysis referred to a hospital context and a blended treatment with a strict 50-50 ratio of web-based and face-to-face interventions. For example, hospital patients could be expected to have a higher health burden and possibly, due to age, a lower internet affinity than the general population. The question arose whether the results would have been different in a healthier, younger population. In addition, as mentioned above, a very strict 50-50 ratio of web-based and face-to-face interventions was defined for BSCT, which did not take into account the individual aspects of both patients and possibly counselors. A blended treatment that is better tailored to the needs, characteristics, and skills of both the patients and the counselors could have possibly led to better results (Wentzel et al., 2016). We know from an earlier paper (L. Siemer, Ben Allouch, et al., 2020) that patients would have preferred to use smartphone apps instead of a web platform, for example, or that they would have liked to be free to choose the ratio and sequence of face-to-face and web-based interventions. At the same time, however, the results did not show any basic patient preferences for BSCT or F2F.

CONCLUSION

In this intermediate six-months analysis of an RCT comparing a blended smoking cessation treatment with a comparable face-to-face treatment, the differences we found in terms of effectiveness indicate an inferiority of the blended treatment. Further practical observations and theoretical modelling should address how these differences in effectiveness can be explained. While the effectiveness of BSCT seemed to be inferior compared to F2F, the patients' satisfaction with both treatments was equally good.

Authorship

LS, MGP, MGJBK, MEP, and SBA initiated collaboration with the data provider, designed the study, and wrote up the study protocol. LS conducted the literature search, monitored data collection, drafted the paper, and is the guarantor of the paper. LS, MGP and MGJBK implemented the trial. LS and MGJBK wrote the statistical analysis plan. LS and MGP designed data collections tools. LS, MGJBK and MEP analyzed the data. LS, MGP, MGJBK, MEP, SBA, and RB revised the draft paper.

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General Discussion

The topic of this thesis - the blending of face-to-face and web-based interventions - and the related question of whether a blended treatment offers “the best of both worlds” (van der Vaart et al., 2014; Wentzel, van der Vaart, Bohlmeijer, & van Gemert-Pijnen, 2016) was taken forward in this thesis in the scope of smoking cessation treatment. The relevance of smoking cessation treatment stems from the fact that smoking cessation treatment can more than double the success rates of smoking cessation attempts (WHO, 2019), thereby significantly reducing the development or deterioration of smoking-related illnesses (WHO, 2020), which continue to kill more than eight million people worldwide each year (WHO, 2019). In order to contribute to the research on smoking cessation treatment and to improve clinical practice, the Blended Smoking Cessation Treatment (BSCT), which is the focus of this work, was addressed by highlighting three themes: user experience, adherence and effectiveness.

Against the background of a randomized controlled trial (Chapter 2: Study Protocol LiveSmokefree-Study), the following questions were examined in detail to find out whether a blended treatment offers “the best of both worlds:

- User experience
  - How is the patients’ user experience in a blended face-to-face and web-based smoking cessation treatment (BSCT) (Chapter 3: User Experience)?
- Adherence
  - How can adherence to BSCT be measured, how adherent are patients, and what predicts patients’ adherence (Chapter 4: Adherence - Measurement, Levels, and Predictors)?
  - How is the adherence to BSCT compared to a face-to-face treatment (F2F), and what predicts adherence to BSCT compared to F2F (Chapter 5: Adherence - Blended vs. Face-To-Face Treatment)?
  - How is the adherence to both modes of delivery (Web-mode; F2F-mode) of BSCT, and what predicts adherence to both modes (Chapter 5: Adherence - Blended vs. Face-To-Face Treatment)?
- Effectiveness
  - Is BSCT at least as effective as F2F in terms of abstinence rates, and are patients more satisfied with either treatment (Chapter 6: Effectiveness - Blended vs. Face-To-Face Treatment)?

In this concluding chapter, these questions will now be answered by drawing on the main findings of the individual studies. Furthermore, limitations will be discussed and implications for clinical practice and future research will be mentioned.

USER EXPERIENCE

User experience (UX) can explain user behavior in general (Castañeda, Muñoz-Leiva, & Luque, 2007; Liébana-Cabanillas, Muñoz-Leiva, Sánchez-Fernández, & Viedma-del Jesús, 2015) and the use of health care services in particular (Haun et al., 2014; Ramtohul, 2015). Since little is known about patients’ user experience (UX) with specifically blended treatments, we investigated whether a blended treatment offers “the best of both worlds” from a UX perspective. To study the UX (Chapter 3: User Experience) of the blended treatment we conducted qualitative interviews with a selection of BSCT patients (n=10) and then analyzed their statements using the UX model of Hassenzahl (Hassenzahl, 2018).

HOW IS THE PATIENTS’ USER EXPERIENCE IN A BLENDED FACE-TO-FACE AND WEB-BASED SMOKING CESSATION TREATMENT (BSCT)?

Patients experienced BSCT predominantly positively. They approached the new form of treatment with the positive-pragmatic attitude of following the treatment and the neutral-open expectation that it would be new and interesting. However, they preferred the F2F-mode to the Web-mode by finding computers unsuitable for them or by fearing that it would be too easy. The usability and utility of BSCT were mostly well experienced, as it was all perceived as clear, simple and helpful. Yet some patients also criticised the web mode of BSCT as they felt it did not suit them or preferred other media such as apps or videos. A special feature of the Hassenzahl UX model is the inclusion of hedonistic aspects such as stimulation, identification, and evocation. According to Hassenzahl (2003), stimulation results from novelty, change and challenge; identification includes attitudes, social position and group membership. And evocation means that products can evoke memories of individually important past events, relationships or thoughts, which therefore can have a symbolic value for the user similar to a souvenir. These hedonic aspects allowed for a differentiated view of the patient experience, and we found that patients experienced BSCT ambiguously in relation to these aspects. While some patients felt stimulated by BSCT to think about giving up smoking, others said they were demotivated because there was nothing new in BSCT and they did not find it interesting. The web sessions in particular were found by many patients to be unsuitable, and thus resulted in a low level of identification. In addition, the web sessions mostly caused negative comparisons, as they reminded the patients of bookkeeping or filling in forms. The different experiences finally resulted in both positive and negative combinations of appeal, feelings and behavior. Some patients experienced more positive consequences: BSCT appealed to be good and they felt for example satisfied and thankful, adhered to the treatment and quit smoking. Other patients experienced more negative consequences: The Web sessions appealed for example nonsense and boring. Ultimately, these patients did not adhere to the treatment and did not quit smoking.

In summary, we concluded that BSCT's UX is characterized by a "hedonistic gap" resulting from the mostly negative identification, stimulation and evocation of the Web-mode. This gap was then compensated for by the F2F-mode, giving an indication that BSCT may be "the best of both worlds", as the strength of one mode (in this case the stronger hedonistic aspects of the F2F-mode) could offset the weaknesses of the other mode. However, this compensation was largely unidirectional: the F2F-mode compensated for the Web-mode but not vice versa.

Although it is not yet clear how relevant hedonistic aspects have been to the effectiveness of BSCT, this seems to be an important observation, as other recent research (Bernecker & Becker, 2020) suggests that hedonism is really just as important as self-control for behavior change aimed at well-being. Although BSCT was generally experienced positively, hedonic aspects such as fun, enjoyment, pleasure and aesthetics seem to be a good opportunity to further develop BSCT (see Implications below).

ADHERENCE

The investigation of adherence has taken up a large part of this research project, because on the one hand - assuming a dose-response-relationship - adherence is a determinant of treatment's effectiveness (Alterman, Gariti, Cook, & Cnaan, 1999; Fish et al., 2009; Sabaté, 2003; Westman, Behm, Simel, & Rose, 1997), and on the other hand adherence is generally low in cessation treatment in general (Kemmeren et al., 2016) as well as in web-based treatment in general (Erbe, Eichert, Riper, & Ebert, 2017). So, what does adherence look like in a blended treatment? How can it be measured? How adherent are patients? And can we identify the predictors of adherence to better understand what is associated with non-adherence?

HOW CAN ADHERENCE TO BSCT BE MEASURED?

As blended treatment was still a relatively new area, we first investigated how to measure adherence in this area and then developed and compared two methods for measuring adherence in BSCT: a complex one, in which the treatment activities of BSCT patients were accurately recorded, and an efficient one, in which only the treatment time was calculated as an indicator of adherence; and we determined the advantages and disadvantages of both methods (Patrinopoulos Bougioukas, 2017; Siemer et al., 2018).

HOW ADHERENT ARE PATIENTS, AND WHAT PREDICTS PATIENTS' ADHERENCE?

Using the first method (activity-based), which we applied to a sample (n=75) of BSCT patients (Chapter 4: Adherence - Measurement, Levels, and Predictors), we found that adherence to

BSCT was rather low, and we found primarily social predictors of higher adherence such as living with a partner and having few smoking friends.

HOW IS THE ADHERENCE TO BSCT COMPARED TO A FACE-TO-FACE TREATMENT (F2F)? WHAT PREDICTS ADHERENCE TO BSCT COMPARED TO F2F?

Interestingly, when using the second method (time-based), which we applied to a larger sample (n=292) to compare BSCT to F2F (Chapter 5: Adherence - Blended vs. Face-To-Face Treatment), the adherence was rather high, and this equally in both treatments. And we found other predictors of higher adherence: a higher age predicted higher adherence to both BSCT and F2F, and a stronger social support predicted higher adherence to F2F.

The seemingly contradictory results on levels of adherence could be explained by differences in the measurement procedures and differences in the analysis, which made the activity-based measurement procedure appear more specific and the time-based procedure more sensitive. Since adherence in blended treatments has hardly been investigated so far (Rasing, Stikkelbroek, & Bodden, 2020), and evidence on validity of adherence measures is still lacking, our two approaches to measuring adherence in blended treatments represent a first contribution to this field. A purely time-based measurement of adherence seems to be more suitable for screening studies, for comparing large samples or for determining how much adherence influences the effectiveness of a treatment, because it focuses on the level of adherence and because it can be performed with little effort. However, it does not allow conclusions to be drawn at the more detailed level, i.e. on the evidence-based techniques for changing behavior within a particular treatment session, as is the case with the activity-based method. Even though the activity-based measurement requires considerable effort and should therefore preferably be used for smaller samples or sub-samples, it is suitable for evaluating individual interventions of a blended treatment, e.g. when the research goal is to understand why adherence is low or where in detail a treatment could be improved.

HOW IS THE ADHERENCE TO BOTH MODES OF DELIVERY (WEB-MODE; F2F-MODE) OF BSCT?

We also used the time-based method to compare the two treatment modes (F2F-mode vs. Web-mode) of BSCT and found that BSCT patients adhered more to F2F-mode than to Web-mode since they spent twice as much time in F2F-mode as in Web-mode.

WHAT PREDICTS ADHERENCE TO BOTH MODES?

Furthermore, the predictors differed between the two modes of BSCT: to be living without children predicted a higher adherence to the F2F mode, while a combination of an extrinsic motivation to quit, a less negative attitude towards quitting and less health complaints did this for the Web mode.

In summary, to compare face-to-face versus blended treatment, the picture was that patients spent similar amounts of time in BSCT and F2F without it being clear whether this was to be considered high or low adherence, as different measurement procedures and evaluations prevented a simple comparison of the two results in the end. However, at least for BSCT, the two measuring methods brought up an interesting point: On the one hand, BSCT patients showed little activity, but at the same time exhausted the planned treatment time. Also, for BSCT it was noticeable that within BSCT the adherence for the two modes was very different. Contrary to the planned 50-50 distribution, patients only used the Web-mode for about 1/3 of the time and the F2F-mode for 2/3 of the time. Was the underuse of the Web-mode compensated by an overuse of the F2F-mode? This could be interpreted as a further indication that in blended treatment one mode of delivery can compensate for the weaknesses of the other. However, as with the UX analysis (see above), the compensation here was only unidirectional again: the F2F-mode compensated for the Web-mode but not vice versa.

For the predictors found, it should be noted that they did not give a consistent picture and, more importantly, only explained small variances. The predictors we found hardly corresponded to those described in the literature on smoking cessation, nor to those that seemed obvious to us, such as Internet skills (Chapter 4: Adherence - Measurement, Levels, and Predictors Chapter 5: Adherence - Blended vs. Face-To-Face Treatment . This suggested that other variables (Sabaté, 2003) such as provider behavior (e.g. treatment fidelity of counsellors), health system factors (e.g. eHealth maturity) and patient characteristics that vary over time (e.g. motivation to stop or attitudes to stop may change during treatment) should be examined in future research.

EFFECTIVENESS

The primary objective of the randomized controlled trial (RCT), which formed the basis of this research project, was to compare the effectiveness of BSCT to F2F (Chapter 2: Study Protocol LiveSmokefree-Study). We expected that BSCT would lead to slightly better abstinence rates than F2F due to the “best of both worlds” idea.

The primary outcome for the comparison was cotinine-validated point prevalence abstinence 15 months after treatment initiation, i.e. 12 months after the expected quit date (expected quit date was 3 months after treatment initiation). Specifically, the RCT was designed as a non-inferiority trial in which was assumed that the abstinence rates of BSCT were not be more than 5 percentage points below those of the F2F. With expected abstinence rates of 15% for BSCT and 10% for F2F, the power calculation then resulted in a sample size of 344

(BSCT:177; F2F: 177). Due to delays in enrolling patients in the RCT, data from the 15-month follow-up for this thesis were not yet fully available for analysis, and therefore the 6-month follow-up interim analysis was used. For this interim analysis (Chapter 6: Effectiveness - Blended vs. Face-To-Face Treatment) we selected two follow-up measurements: 3 months after the start of treatment, which corresponded to the expected quit date; and 6 months after the start, which corresponded to 3 months after the expected quit date and at the same time the end of treatment.

IS BSCT AT LEAST AS EFFECTIVE AS F2F IN TERMS OF ABSTINENCE RATES?

Contrary to our expectations, we did not find any evidence of non-inferiority of BSCT to F2F. The most important measurement - cotinine-validated point prevalence abstinence - showed significantly lower abstinence rates of BSCT (4.8%) compared to F2F (17.5%) in the intention-to-treat analysis (difference of 12.7 (95% CI 6.2-19.4); P<.001). Based on a Bayes factor calculation, we interpreted this difference as very strong evidence for the inferiority of BSCT. However, this result should be treated with caution, as unfortunately very few cotinine samples were available for analysis and the distribution was uneven: There were considerably more samples available for the F2F group than for the BSCT group. So here it could be that due to missing data we have to assume a confounding. This assumption is also supported by the fact that this significant inferiority was not confirmed in the CO measurements, nor in two of the four self-reported abstinence measurements. Conversely, as we also did not find evidence for non-inferiority or superiority of the BSCT in any measurement, we therefore assume that BSCT was inferior.

ARE PATIENTS MORE SATISFIED WITH EITHER TREATMENT?

Interestingly, however, this inferiority was not found in patient satisfaction, which was also evaluated in this interim analysis. Both treatment groups rated their own treatment results, the treatment, and the counsellors equally good.

In summary, we conclude from this interim analysis - although this is not yet entirely clear due to inconsistent results - that BSCT is not as effective as F2F in terms of abstinence rates, although patients are equally satisfied with both treatments. This contradicted our expectations and the previous findings from other RCTs that favored blended over F2F treatments (Carroll et al., 2008; Christensen et al., 2014) and supports Blankers (2020) call for new studies to explore what the optimal intensity of digital interventions, and what amount of face-to-face or on-line guidance is necessary.

BLENDED TREATMENT - THE BEST OF BOTH WORLDS?

Hovering over this research project was the idea that blended web-based and face-to-face treatment could be a valuable development in the field of eHealth, combining “the best of both worlds” (van der Vaart et al., 2014; Wentzel et al., 2016), as the strengths of one approach could compensate for the weaknesses of the other. Looking now at the results of the above-mentioned sub-studies, a mixed picture emerges. We have found indications that in BSCT the strengths of one approach outweigh the weaknesses of the other. But this was only unidirectional: the strengths of the F2F-mode compensated for the weaknesses of the Web-mode, as was shown in the user experience description and in the analysis of adherence to BSCT. If this is only possible in one direction, is it really a strength? Because it also means that some effective components of the treatment, which are only offered in Web-mode, are not used at all and thus question the effectiveness of the treatment, which is then also reflected in the partly lower abstinence rates in BSCT. At the same time, the lower use of Web-based treatment, which is also connected with the idea of reducing costs, is compensated with more cost-intensive F2F treatment. This should have a negative effect on the cost-effectiveness.

Thus, it seemed that the web-based part of BSCT could not bring any strengths into the interaction of the two treatment modes. If one then considers that BSCT partially leads to lower abstinence rates - i.e. appears less effective - compared to F2F, while adherence, measured as treatment time, was the same for both treatments, BSCT appears less efficient. This would mean that, contrary to our expectations, BSCT would not have any relevant advantages.

However, when we look at the UX and adherence results, the picture emerges that BSCT appeared positive at least for a subset of patients. Three of our ten interviewed patients reported a rather positive user experience, adherence and treatment success. BSCT appealed to be “good” and they felt “satisfied” or “thankful,” followed the treatment and quit smoking (Chapter 3: User Experience). For this smaller group of patients, the positive expectations that blended treatment makes care more customer-friendly, better quality and more targeted (Postel, Witting, & Gemert-Pijnen, 2013) seemed to be fulfilled. Here we can assume a target group that could benefit from blended treatment and which should be more precisely defined in order to offer them blended treatment as an alternative to face-to-face treatment in the sense of freedom of choice. This group could then also benefit from the secondary advantages of blended treatment such as for example reduced travel time and costs due to the lower number of visits to the clinic. However, the positive results do not automatically apply to the entire group of smokers. At least they could not be experienced by all smokers with this realization of a blended treatment.

IMPLICATIONS

CLINICAL PRACTICE

In terms of clinical practice, our results show that the adherence and user experience of the web parts of the blended treatment offer potential for improvement. It seems that in this realization of a blended treatment especially the web-based parts did not really touch the majority of patients and therefore the expected potential of a blended treatment could not be realized. If BSCT is to be experienced positively for a larger group of patients in the future, it clearly should be improved. The starting point for improvements could be a revision of the web-based parts in particular (e.g. offering the smoking register as a smartphone app instead of the cumbersome web software) that involves patients more closely and builds more on user-centered design (Norman & Draper, 1986) in the form of participatory design (Simonsen & Robertson, 2012) e.g. using the CeHRes Roadmap (van Gemert-Pijnen et al., 2011). Even though this research did not focus on the questions whether the lower performance of BSCT was caused by weaknesses in the design process of the treatment, it should be noted that the non-involvement of patients in the design process of the BSCT excluded one of the main stakeholders. This should be taken into account in any revision.

Also, the inclusion of approaches such as nudging (Vlaev, King, Dolan, & Darzi, 2016), funology (Hassenzahl, 2003, 2018) or persuasive system design (Kelders, Kok, Ossebaard, & Van Gemert-Pijnen, 2012; Lehto & Oinas-Kukkonen, 2011) in the web interventions could improve the user experience and the adherence. For example, patients find it more persuasive if the web-based treatment parts were technically implemented as an app for their smartphone and not as a website for PCs (Chevalking, Ben Allouch, Brusse-Keizer, Postel, & Pieterse, 2018). Another example would be personalization by making the blended treatment more flexible. In consultation with their counselors, patients should be free to choose whether and if so, which parts of the treatment are web-based, and which are face-to-face. Practical instruments to support decision-making can be, for example, the “Fit for Blended Care” instrument (Wentzel et al., 2016) or an adaption of the “Blended Physiotherapy Checklist” (Kloek, Janssen, & Veenhof, 2020).

FUTURE RESEARCH

Our project also raised some interesting questions regarding further research. For example, from the perspective of the user experience, questions remained open, whereby the question of what role hedonism played for the success of blended treatment seemed particularly fruitful to us (Chapter 3: User Experience). The idea that hedonistic aspects such as stimulation, identification and evocation (Hassenzahl, 2003, 2018) are relevant to the user experience in addition to utility and usability opens up new approaches to involve the user experience more strongly in the development in order to release the “power of

pleasure" (Bernecker & Becker, 2020). Formulated from the patient perspective, future research should address questions such as "When do I experience 'a' blended treatment as 'my' treatment?"; "When does a blended treatment bring me ideas and inspirations that are both new and at the same time tie in with familiar ones?"; "What must a blended treatment look like so that it feels 'made for me' and I don't experience it like filling out a tax return?"; "How much fun can I expect from a blended treatment and how much fun is effective?", or "How can I avoid that a blended treatment evokes negative associations in me and that I therefore do not continue the treatment?"

In addition, we investigated adherence in blended treatment but ultimately could not clarify how best to measure adherence in blended treatment and what degree of adherence would be optimal for efficient treatment (Chapter 4: Adherence - Measurement, Levels, and Predictors Chapter 5: Adherence - Blended vs. Face-To-Face Treatment . Future research should address which method for measuring adherence to a blended treatment is appropriate for which research questions. We think that the activity-based method is recommendable. However, it should still be explored how to implement it efficiently in research practice. For example, by considering this data collection early on in the research design.

Also, the determination of the predictors of adherence and thus - based on the assumption of a dose-response relationship - ultimately also of effectiveness should be explored further. From the predictors we found in the demographic, smoking and health characteristics of the patients, no meaningful pattern emerged, and these predictors also explained only a small variance in adherence. This raises the question of which other characteristics played a role, e.g. from the provider side the user experience of the counsellors or challenges in treatment fidelity such as therapist drift (G. Waller, 2009; Glenn Waller & Turner, 2016), Such characteristics have not been systematically evaluated. We have also only considered the group of users here. However, an innovation process (here the introduction of BSCT) is influenced by various determinants (Fleuren, Paulussen, Van Dommelen, & Van Buuren, 2014): the socio-political context (here: the uptake of digital health interventions), the character of the organization (here: hospital), the users (here: counselors, patients), the innovation (here: BSCT) and the innovation strategy (here: integration into an RCT). Investigation of these further determinants could provide a better picture of the potential of introducing BSCT. For examples, the professionals hold a key role for the uptake of digital health interventions and are more open to these in countries with advanced implementation of digital health services and after having first-hand experience (Schuster, Topooco, Keller, Radvogin, & Laireiter, 2020). According to the Digital Economy and Society Index (DESI), the Netherlands is among the world leaders in digitization (European Commission, 2019) and thus a forerunner in the introduction of digital health services, but - in our case - professionals

lacked first-hand experience. The influence of this lack should be given more attention.

It also needs to be further clarified how an optimal matching of patients and treatment could have been achieved: Which type of blended treatment fits which patient? Looking at the results of the UX and adherence studies, it seems that BSCT better suits patients with higher age, higher social support, lower health problems and less need for hedonism. However, these characteristics make us think of personality traits such as stability and conscientiousness that are usually not associated with increased tobacco use (Malouff, Thorsteinsson, & Schutte, 2006; Terracciano & Costa, 2004). And these are of course also characteristics that fundamentally improve the therapy prognosis in smoking cessation treatment (Nieva et al., 2011). Would BSCT then be suitable above all for people who smoke very little on the one hand and are also easily treatable on the other, i.e. for "ideal patients" or "mild cases"? And vice versa: should more unstable and unreliable patients then be better treated with more face-to-face interventions?

Finally, there is still an open question after this project with regard to targeting: Would the results have been different in a different clinical setting with a different target group? We have studied BSCT in the smoking cessation clinic of a hospital and, based on the UX and adherence studies, we assume that both the clinic and the patients operated with a face-to-face "default mode". The web components of BSCT were therefore the new and possibly strange. It is possible that the results for BSCT would have been different if the studies had been conducted in a web setting (e.g. in the web department of Tactus Addiction Care). Thus, if patients and care providers with a basic web "default mode" had been subject to an addition of face-to-face interventions, the question would arise as to whether BSCT would then had been non-inferior or even superior.

CONCLUDING THOUGHTS

For this research project we have approached the idea of a blended treatment with positive expectations, as we believed that this form of treatment fits better to the current lifestyle of patients and professionals. Our research contributes to evidence of treatments effectiveness, theory of behavioral change, theory of user experience in eHealth, and research methodology. If we now look at the results of the studies, their methodological consideration, and their implications, we find that not every realization of blended treatment automatically is also an improvement. With this realization - Blended Smoking Cessation Treatment - it seems that the expected potential of blending face-to-face and web-based interventions has not been unleashed. This research project, which has provided many detailed findings on the subject of blended treatment, is thus sharpening the eye for a

better type of blended treatment in the future, so that the potential of this up-to-date and innovative approach, which is intended to combine the “best of both worlds”, can be fully realized. Smoking is still a deadly epidemic, and the path out of tobacco addiction is often marked by many futile attempts. It is therefore worthwhile to look for new approaches or new combinations of proven approaches that will significantly improve smoking cessation treatment, although sometimes perhaps only to a small extent. After all, innovative and effective smoking cessation treatment remains one of the best ways of effectively supporting smokers on their way to a self-determined, healthy life.

> *And how is Alexandra now? She has gone through the treatment and thought it was really good that she didn’t have to go to the clinic so often. The meetings at the clinic with the counsellor were quite demanding, but it did her good, because the talks were informative and intensive. She found the computer tasks at home okay, some she found useful, some less so. In the end Alexandra did not stop smoking, but she has been smoking significantly less since the treatment. From her point of view, this stop attempt has taken her a step further on the road to not smoking. And she would do the treatment again.*

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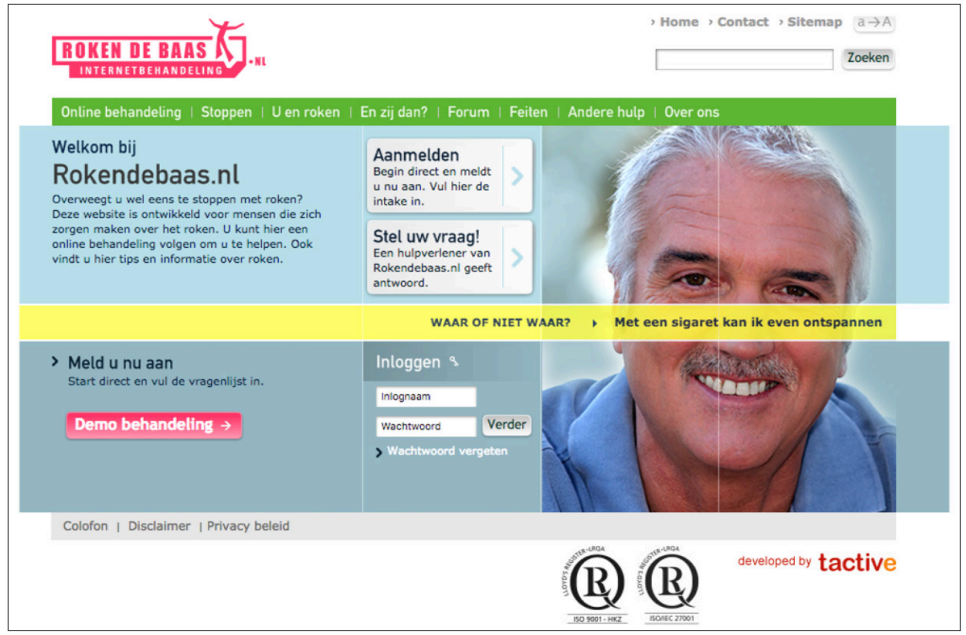
Multimedia Appendix 1.
Multimedia Appendix 2.
Summary *(English)*
Samenvatting *(Dutch)*
Zusammenfassung *(Deutsch)*
Acknowledgements/Dankwoord/Dankworte
Curriculum Vitae
Publications and Presentations

MULTIMEDIA APPENDIX 1: SCREENSHOTS OF THE WEB-SESSIONS OF BSCT

In the following, screenshots of the web-sessions of BSCT are provided in order to give an impression of its look and feel. Note: The language of the web content was Dutch. Therefor a comprehensive English description is added.

LANDING PAGE

The landing page at www.rokendebaas.nl offered the possibilities to register and log in, to follow a “demo-treatment” and to find information about smoking and smoking cessation.

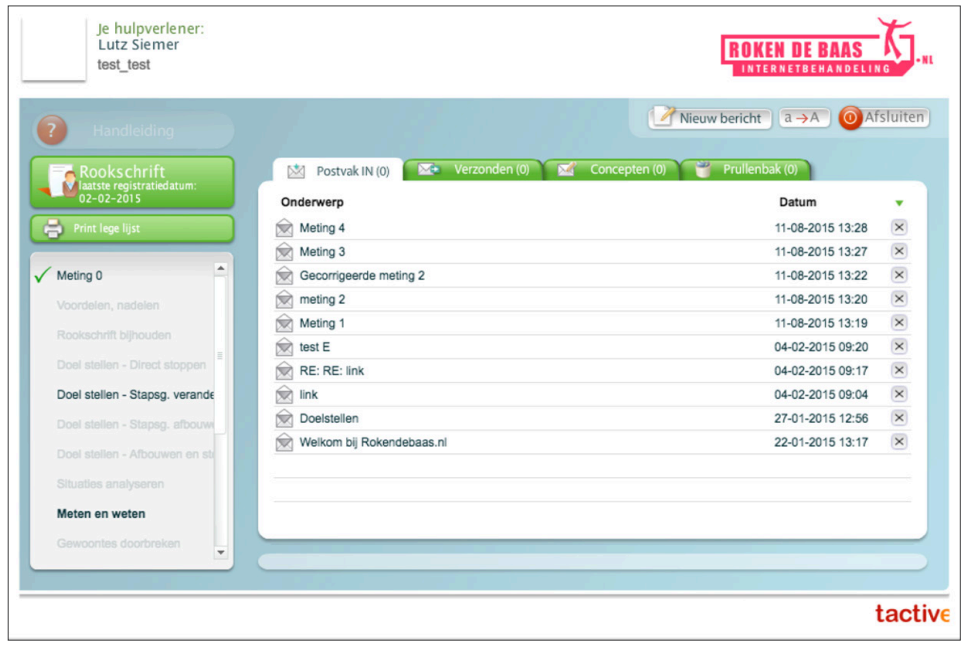


STARTING PAGE OF THE TREATMENT

Once logged in, patients chose to proceed with going to their record (“Dossier”), to the smoking self-recording (“Rookschrift”), or the to the forum to exchange with peers. In addition, if new messages (from example from the counselor) were available was also displayed here (“Berichten”).

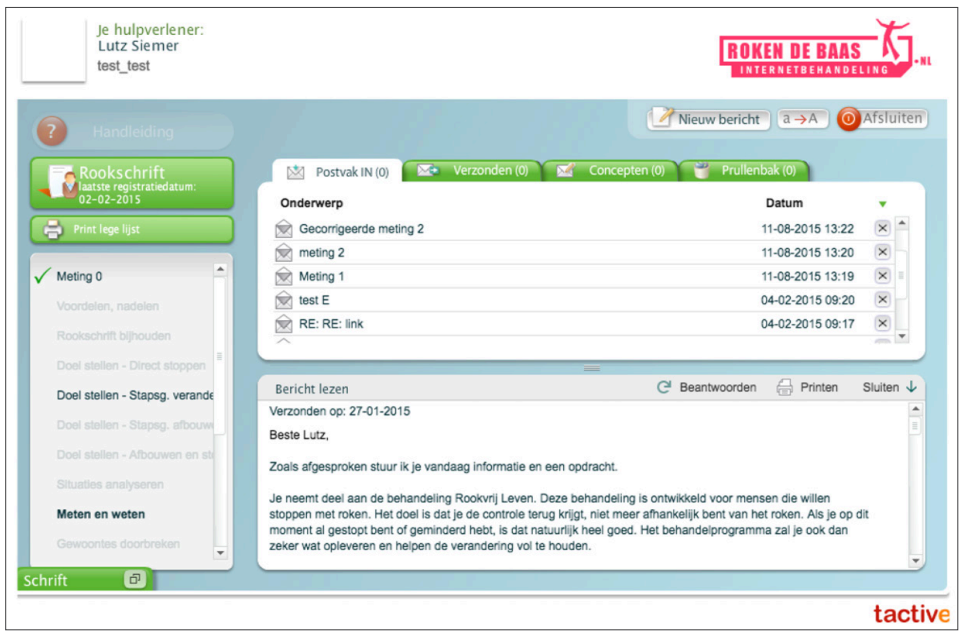
INBOX

This was the inbox of the integrated messaging system for patients and counselors. In addition, patients could go directly to their smoking self-recording (Rookschrift”) and to the interventions which were already unblocked by the counselors. In this case, the patient could go directly to “Goal setting (“Doel stellen - … “) or to “Measuring and Knowing (“Meten en weten”.)



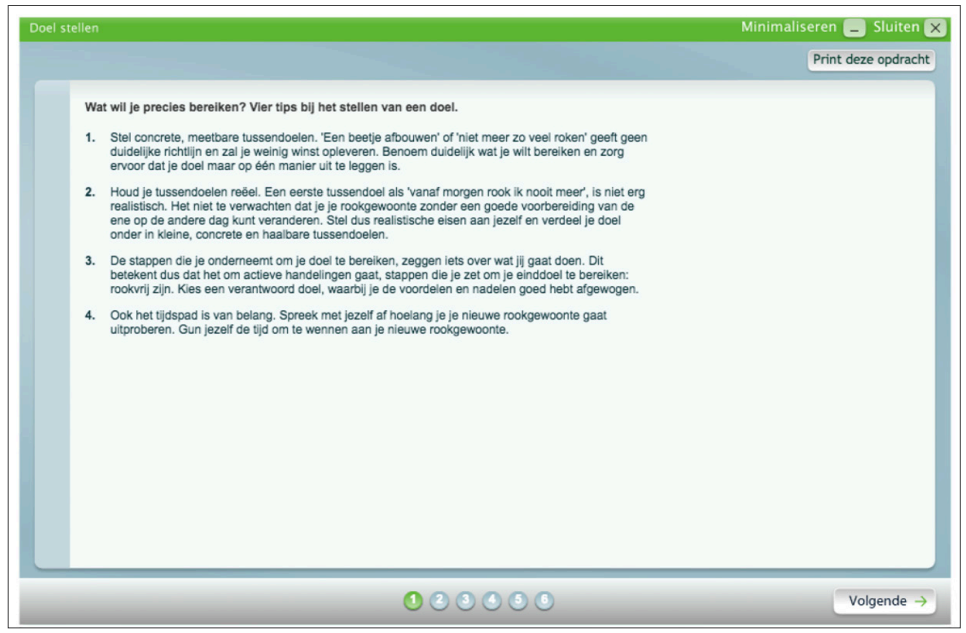
READING MESSAGES

The inbox after opening a message. Patients had the option to reply, print or close the message.



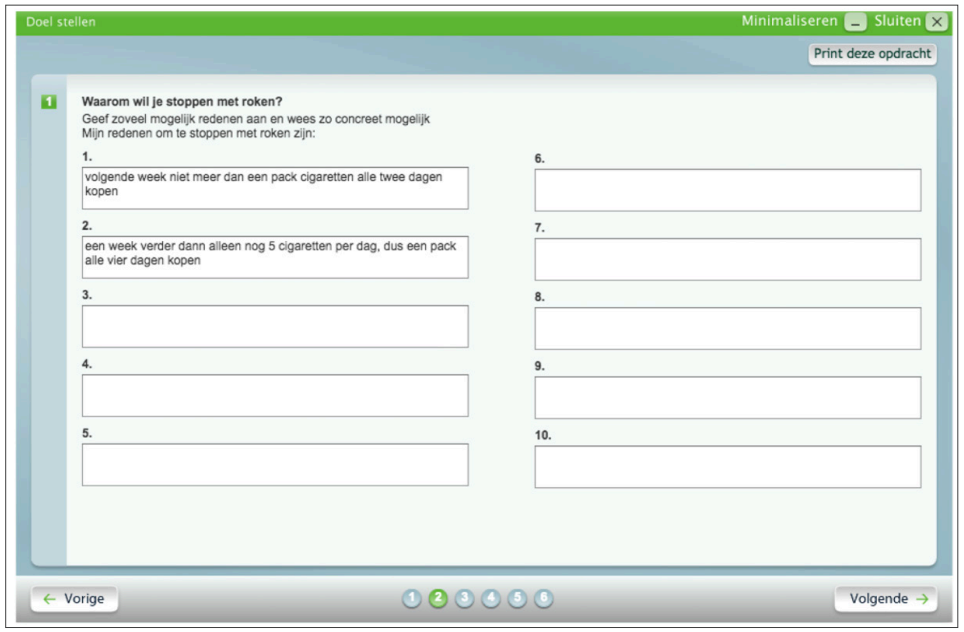
GOAL SETTING

This was the first page of the goal setting intervention where the patient was asked to think about what he/she wanted to achieve precisely. In addition, four tips for goal setting were provided.



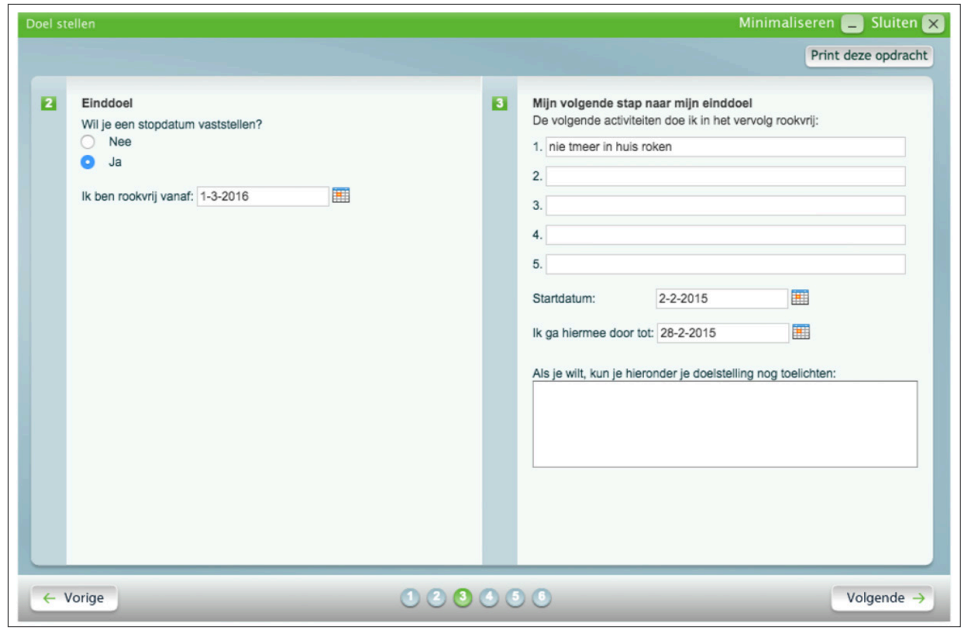
WHY DO YOU WANT TO STOP SMOKING (“WAAROM WIL JE STOPPEN MET ROKEN”)?

The second page of the goal setting intervention where the patient were asked to fill in as many reasons as possible and to do this as precisely as possible.



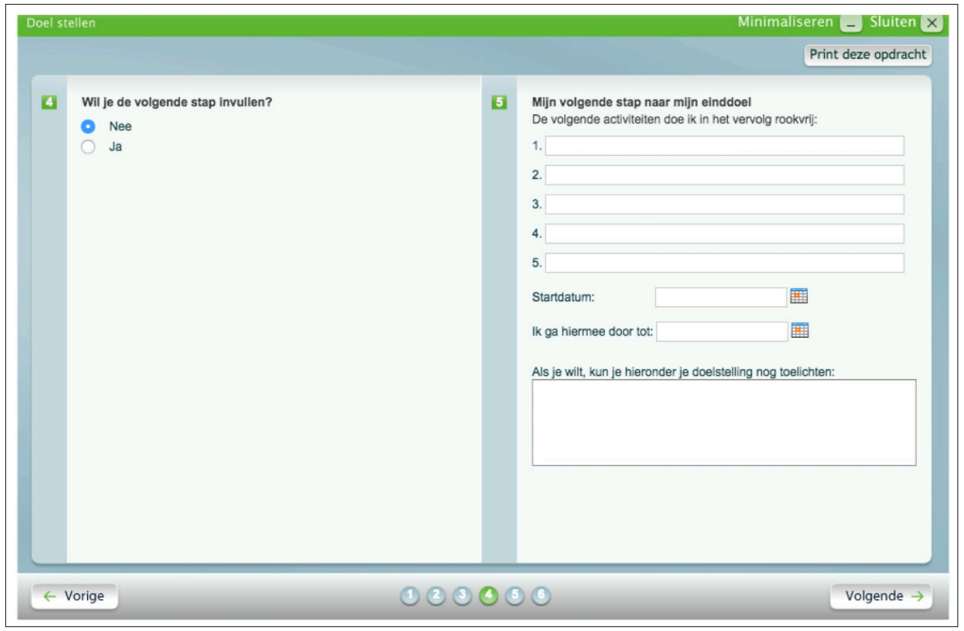
FINAL GOAL (“EINDDOEL”)

Third page of the Goal setting intervention, where the patient were asked if he/she will fix a stop date (Einddoel”) and which smokefree activities he/she will do when (“mijn volgenden stap naar mijn einddoel”).



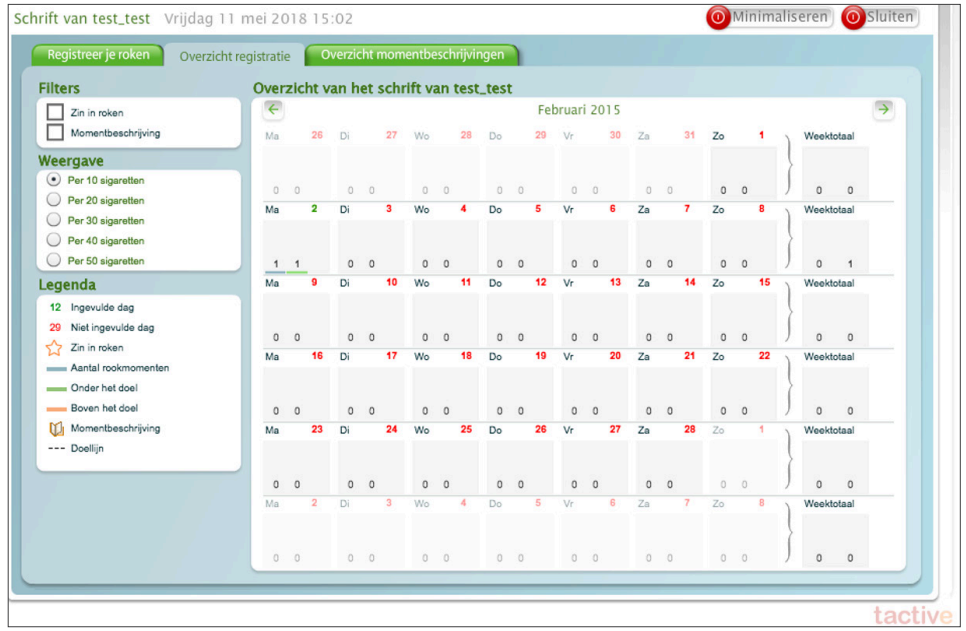
MORE GOALS

Fourth page of the goal setting interventions where the patient may have added more goals and activities.



SMOKING SELF-RECORDING

Overview of the smoking self-recording (“Overzicht registratie”) where the patient’s registry of numbers of cigarettes and the moment descriptions were displayed.

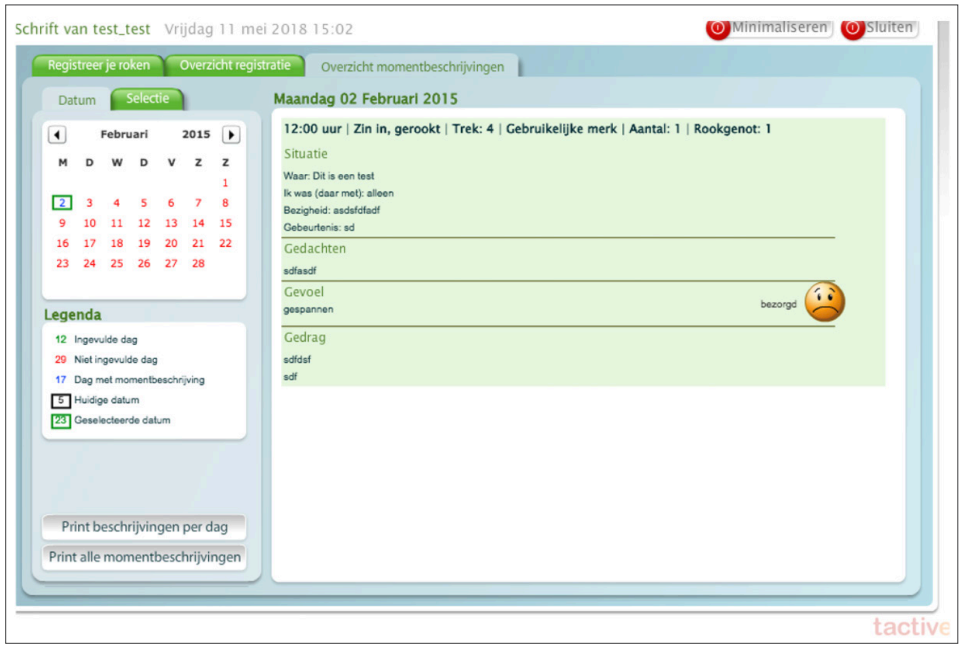


MOMENT DESCRIPTIONS

Here the patient could record the following characteristics for a smoking situation:

Time of day
Cigarette brand
Level of smoking pleasure
Emotions
Situation
Level of craving
Number of cigarettes smoked
Thoughts
Behavior

Furthermore, patients could print moment descriptions (either all or per day).



MULTIMEDIA APPENDIX 2: BSCT UX INTERVIEW GUIDE (DUTCH)

THEMALIJST EN VRAGEN UX BSCT

Termen die die counselors gebruiken

- “Combi” behandeling
- “Online”
- “afspraken op de poli”

VOORBEREIDING EN INTRODUCTIE

VOORBEREIDING

- Stel voor om aan een tafel plaats te nemen, bij voorkeur in een kamer waar geen anderen aanwezig zijn.
- Ga zo zitten dat de respondent moeilijk kan meelezen met wat er op papier staat of wat je opschrijft (bijvoorbeeld aantekeningen).
- Geef aan dat je het interview graag wilt opnemen en dat de opname alleen wordt gebruikt om een gespreksverslag te maken en dat de opname na afloop van het onderzoek wordt vernietigd.
- Vraag aan de respondent of hij/zij het goed vindt dat het gesprek wordt opgenomen.
- Pak de nodige materialen en zet de opnameapparatuur klaar
- Laat de respondent de toestemmingsverklaring in tweevoud dateren en ondertekenen en doe dat zelf ook.
- Geef een van de exemplaren aan de respondent, het andere exemplaar dient gearchiveerd te worden op Onderzoeksbureau Longgeneeskunde.
- Geef aan dat je, voordat je van start gaat met het interview, een testje wil doen met het opnameapparaat.
- Schakel het apparaat in spreek in: “test”, de datum van vandaag en het tijdstip”
- Vraag aan de respondent of hij de datum en het tijdstip wil herhalen.
- Spoel de opname terug en verzeker jezelf ervan de geluidsopname goed is. Pas zo nodig het geluidsniveau en/of de opstelling aan en herhaal de test totdat de geluidsopname goed is.
- Kondig aan dat je klaar bent om met het interview te beginnen.

INTRODUCTIE

“(Nogmaals) hartelijk dank dat u mee wilt werken aan dit interview. Wij verwachten dat dit interview tussen 60 en 90 minuten gaat duren. Door het afnemen van interviews proberen we inzicht te krijgen in de ervaringen van deelnemers aan de gecombineerde online en face-to-face behandeling. In de rest van dit interview zullen wij deze gecombineerde behandeling “de combi behandeling” noemen. De uitkomsten geven ons meer inzicht in uw ervaring met de combi-behandeling voor stoppen met roken en helpt ons waar nodig deze behandeling te verbeteren.

“Het interview heeft geen invloed op uw behandeling op de afdeling Longgeneeskunde. De behandelaars, bijvoorbeeld uw longarts of de medewerkers van de stoppen-met-roken poli, krijgen geen informatie over wat u hier vertelt”.

“Uw persoonsgegevens worden strikt vertrouwelijk behandeld en de gegevens die u tijdens het interview verstrekt worden anoniem verwerkt en zijn op geen enkele manier tot u te herleiden.”

“Zoals u weet zijn we geïnteresseerd in de ervaringen van mensen die de combi behandeling voor stoppen met roken gevolgd hebben tijdens hun deelname aan de RookvrijLeven-studie en zijn we benieuwd hoe zij dit, ieder op hun eigen manier, hebben ervaren. Wij willen u daarom vragen om uw ervaringen met de combi behandeling te vertellen; we horen graag alle ervaringen en gebeurtenissen die daarbij belangrijk waren voor u persoonlijk.”

“Dus uw mening over en beleving van de behandeling staat centraal bij dit interview. Wij beschouwen u als de expert”.

“Neemt u alstublieft alle tijd die u nodig heeft. Wij zullen vooral luisteren en proberen om u niet te onderbreken. Wij zullen af en toe aantekeningen maken.”
“Heeft u nog vragen vooraf?“

BEHANDELSTAPPEN

Om onze vragen beter te kunnen toepassen aan uw situatie willen wij aan het begin weten welke van die volgende behandelstappen u zich herinnert gevolgd te hebben. Welke van deze behandelstappen herinnert u zich?

Stappen (sessie)	Inhoud	
(1) face-to-face	Doel stellen Registratieschrift	❑
(2) online	Registratie bespreken Zelfcontrolemaatregelen Medicatie	❑
(3) face-to-face	Registratie bespreken Omgaan met trek	❑
(4) online	Registratie bespreken Uitlokkers	❑
(5) face-to-face	Registratie bespreken Omgaan met uitlokkers	❑
(6) online	Registratie bespreken Stof tot nadenken	❑
(7) face-to-face	Registratie bespreken Anders denken	❑
(8) online	Registratie bespreken Anders doen	❑
(9) face-to-face	Registratie bespreken Actieplan	❑
(10) online	Registratie bespreken Afsluiting	❑

VRAGENLIJST

ALGEMENE ERVARINGEN MET DE COMBI BEHANDELING

Themalijst:

Ervaringen algemeen	❑
Dingen die goed/slecht gingen	❑
Ervaringen met de counselor f2f	❑
Ervaringen met de counselor online	❑
Verwachtingen algemeen	❑
Verwachtingen online	❑
Verwachtingen face-to-face	❑
Verwachtingen counselor	❑
Eerdere ervaringen combie	❑
Eerdere ervaringen face-to-face	❑
Eerdere ervaringen online	❑
Eerdere ervaringen computer & internet	❑
Zelfbeschrijving computergebruik	❑
Ervaring blended communiceren	❑
Invloed ervaringen	❑

“Kunt u ons, om te beginnen, vertellen wat uw ervaringen zijn met de combi behandeling? Alle gebeurtenissen en ervaringen die belangrijk voor u waren horen we graag.

Doorvragen kan altijd door…

“U noemt …. . Kunt u er meer over vertellen?”

“U noemt … . Kunt een voorbeeld geven?”

“Zijn er naast de dingen die goed gingen ook dingen die minder goed gingen?”

“Zijn er naast de dingen die minder goed gingen ook dingen die juist wel goed gingen?”

Vragen over verandering tijdens de behandeling (vooraf, begin, tijdens, aan het eind, nu terugkijkend), b.v.

“U noemt ….Was dat ook aan het begin al zo?”

“Is er gedurende de behandeling iets veranderd in uw opvatting over… ?”

Volgende vraag alleen stellen als de respondent veranderingen noemt.

„U noemt … Wat maakt dat er een omslag is geweest in uw ervaring? Op welk punt van de behandeling was dit ongeveer?“

“Kunt u Zich de reden hiervoor nog herinneren?”

Doorvragen naar counselor tegenover online.

“Wat zijn uw ervaringen met het contact met de counselor op de poli?”

“Wat zijn uw ervaringen met het contact met de counselor online?”

[Doorvragen.. zijn hier tegenstrijdigheden in?]

VERWACHTINGEN EN ERVARINGEN VOORAF

“Wij willen graag iets dieper ingaan op uw verwachtingen van de combi behandeling en ervaringen voorafgaand aan deze combi behandeling”

“Welke verwachtingen had u van de combi behandeling toen het duidelijk was dat u deze behandeling ging volgen?”

“Welke verwachtingen had u van het online gedeelte van de behandeling?”

“Welke verwachtingen had u over de afspraken op de poli?”

“Welke verwachtingen had u over de counselor?“

„Welke eerdere ervaringen had u met face-to-face behandeling voor uw gezondheid zoals hier op de poli?”

„Welke eerdere ervaringen had u met online behandeling voor uw gezondheid?”

„Welke eerdere ervaringen had u in het algemeen met computer en internet?”

“Hoe zou u zichzelf beschrijven als het gaat om computergebruik in het algemeen?”
„U kent nu de combi behandeling. Had u voorafgaand aan deze behandeling reeds ervaring met online communiceren in combinatie met face-to-face afspraken? Denk hier bijvoorbeeld aan afspraken via e-mail/vergaderen, whatsapp of iets dergelijks. Kunt u daar iets over vertellen?”

Evtl. doorvraag..
“Denkt u dat dit invloed heeft gehad op de combi behandeling?”

GEBRUIKER

Themalijst:

Reden stoppen/doorgaan met behandeling	❑
Combi motiveert stoppen met roken	❑
Helpende onderdelen	❑
Motivatie door counselor	❑
Counselor leest informatie	
Stemming	❑
Verandering stemming	❑
Behandeling passend bij patiënt	❑
Eigenschappen/vaardigheden voor het volgen van de combi	❑

“Wij willen het nu graag over u als deelnemer hebben. We vragen bijvoorbeeld naar uw motivatie of over hoe het met u ging tijdens de behandeling.”

MOTIVATIE BIJ HET VOLGEN VAN DE COMBI BEHANDELING

“Wat maakt dat u met de behandeling bent gestopt?”

OF

“We weten dat het best lastig kan zijn om een stoppen met roken behandeling vol te houden tot het eind. Dat lukt u echter goed. Wat maakt dat u het goed volhoudt om deze behandeling te volgen?”

Check informatieblad respondent wat van toepassing is.
[De volgende vraag alleen stellen als de respondent geen toelichting geeft op de reden voor stoppen/doorgaan]
“Kunt u toelichten waarom .....[reden(en) noemen] de reden was?”

De volgende vraag aan alle respondenten stellen.
“Waren er naast ...[reden(en) noemen] voor u nog andere redenen om te stoppen/ door te gaan?”
“In hoeverre motiveerde deze gecombineerde behandeling u bij het stoppen met roken?”
“Wat was voor u het meest motiverende onderdeel van de combi behandeling?“
“Was dat meer iets wat in het face-to-face gedeelte of in het online gedeelte gebeurde?”
“Welke onderdelen hielpen u het meest om te stoppen met roken?”
“Welke onderdelen hielpen u niet of minder bij stoppen met roken?”
“In hoeverre motiveerde de counselor u? En maakte het voor u verschil of het een online contact of het een afspraak op de poli betrof?”

Evtl. doorvragen...
“Hoe bewust was u van het feit dat de counselor de online informatie leest? In hoeverre heeft dat uw ervaring met de combi behandeling beïnvloed?”

STEMMING BIJ HET VOLGEN VAN DE COMBI BEHANDELING

“Stoppen met roken gaat meestal gepaard met de nodige stemmingen en emoties. U kunt hierbij denken aan bij voorbeeld vreugde of verdriet, woede, angst, verbazing of walging. “
“Welke emoties heeft u met name ervaren?

“Zijn er veranderingen in uw gemoedstoestand geweest?”

Als deelnemer iets noemt doorvragen ...
“Wanneer was dat? Bij welke onderdelen van de behandeling?”

Doorvragen naar betere stemming als alleen slechtere wordt genoemd, en andersom ...
„Heeft u ook een betere/slechtere gemoedstoestand ervaren ?“

Als deelnemer iets noemt doorvragen ...
“Wanneer was dat? Bij welke onderdelen van de behandeling?”

RESSOURCES TIJDENS HET VOLGEN VAN DE COMBI BEHANDELING

“Vindt u deze manier van behandelen passend bij u?”

„Waren er specifieke onderdelen die u vooral passend vond bij uzelf?“
„Om de combi behandeling goed te kunnen volgen is het belangrijk dat iemand o.a. voldoende computervaardig en gemotiveerd is. Herkent u dit? Wat zijn volgens u nog meer eigenschappen/vaardigheden die belangrijk zijn voor het kunnen volgen van een combi behandeling?“

De volgende vraag alleen stellen als de respondent geen toelichting geeft op de vaardigheden
"Kunt u toelichten waarom .....[vaardigheid noemen] nodig is?"

Eventueel doorvragen naar fysieke/mentale ressources

CONTEXT

Themalijst:

Mensen rondom heen	❑
Verschillende plekken	❑
Vrijheid vs. structuur	❑
Voorlichting	❑
Techniek	❑

"Wij willen ook graag weten wat er rondom de behandeling heen gebeurde. Wat zeiden de mensen in uw omgeving? Wat vond je van de behandelplekken – hier op de poli of thuis? We zullen met de mensen in uw omgeving beginnen."

SOCIALE CONTEXT TIJDENS HET VOLGEN VAN DE COMBI BEHANDELING

"Waren mensen in uw omgeving op de hoogte van uw deelname aan de combi behandeling?
"Waarom wel / niet? Kunt u dat toelichten?"

"In hoeverre werd uw ervaring met de combi behandeling beïnvloed door mensen in uw omgeving? Denk hierbij aan familie, collega's, vrienden en anderen … wat zij dachten, zeiden of deden."

"In hoeverre werd u gemotiveerd (of juist niet) door mensen in uw omgeving?"

FYSIEKE CONTEXT TIJDENS HET VOLGEN VAN DE COMBI BEHANDELING

"Op welke plekken heeft u de online onderdelen van de behandeling gevolgd? Waarom op deze plek?
"Wat vond je van het feit dat je het ene moment achter je eigen computer zat en het andere moment in de spreekkamer op de poli?"

TAAK CONTEXT TIJDENS HET VOLGEN VAN DE COMBI BEHANDELING

"Het online gedeelte van de behandeling is behoorlijk gestructureerd, terwijl de afspraken op de poli wat meer vrijheid kennen. Hoe kijkt u hier tegen aan?"
"Wat vond u vooral prettig aan de vrijheid / vaste structuur?"

Evtl. doorvragen naar afleiding door andere taken bij het online gedeelte.
"Hoe druk bent u geweest met die combi behandeling?"
"Hoe druk bent u geweest met andere taken tijdens de combi behandeling?"

TECHNISCHE EN INFORMATIEVE CONTEXT TIJDENS HET VOLGEN VAN DE COMBI BEHANDELING

"Wat vind u van de voorlichting die u hebt gekregen over de combi behandeling?"
"Had de computer die tot uw beschikking stond invloed op uw ervaring met de behandeling?"

EVALUATIE

Themalijst:

Gebruiksvriendelijkheid	❑
Gebruiksvriendelijkheid "online"	❑
Gebruiksvriendelijkheid "face-to-face"	❑
Verbeterpunten gebruiksvriendelijkheid	❑
Vanzelfsprekendheid	❑
Vanzelfsprekendheid "online"	❑
Vanzelfsprekendheid "face-to-face"	❑
Verbeterpunten vanzelfsprekendheid	❑
Toegankelijkheid	❑
Toegankelijkheid "online"	❑
Toegankelijkheid "face-to-face"	❑
Verbeterpunten toegankelijkheid	❑
Tevredenheid "algemeen"	❑
Tevredenheid "online"	❑
Tevredenheid "face-to-face"	❑
Verbeterpunten tevredenheid	❑
Verdeling face-to-face en online gedeelte	❑
Voordelen/Nadelen	❑

GEBRUIKSVRIENDELIJKHEID VAN DE COMBI BEHANDELING

"We willen het graag hebben over de gebruiksvriendelijkheid van de gecombineerde behandeling, denkt u hierbij aan vanzelfsprekendheid, het gemak in gebruik en toegankelijkheid."
"Kunt u vertellen wat uw ervaringen zijn met de gebruiksvriendelijkheid?"

"Kunt u hier voorbeelden van geven?"
"Waar denkt u dat er verbeteringen kunnen worden aangebracht in het programma?"

De volgende vragen alleen stellen als de respondent geen toelichting geeft op gebruiksvriendelijkheid van het online gedeelte van de combi behandeling.
"Hoe gebruiksvriendelijk vond u het online gedeelte van de combi behandeling?"
"Kunt u hier voorbeelden van geven?"
"Waar denkt u dat er verbeteringen kunnen worden aangebracht in het online deel van de combi behandeling?"

De volgende vragen alleen stellen als de respondent geen toelichting geeft op gebruiksvriendelijkheid van het face-to-face gedeelte van de combi behandeling.
"Hoe gebruiksvriendelijk vond u het face-to-face gedeelte van de combi behandeling?"
"Kunt u hier voorbeelden van geven?"
"Waar denkt u dat er verbeteringen kunnen worden aangebracht in het face-to-face deel van de combi behandeling?"

De volgende vragen alleen stellen als de respondent geen toelichting geeft op vanzelfsprekendheid van het online gedeelte van de combi behandeling.
"Wat is uw ervaring met betrekking tot vanzelfsprekendheid in het online gedeelte van de combie behandeling?"
"Kunt u ons hier wat meer over uw ervaringen vertellen?"
"Kunt u hier voorbeelden van geven?"
"Waar denkt u dat er verbeteringen kunnen worden aangebracht in de combi behandeling?"

De volgende vier vragen alleen stellen als de respondent geen toelichting geeft op vanzelfsprekendheid van het face-to-face gedeelte van de combi behandeling.
"Wat is uw ervaring met betrekking tot vanzelfsprekendheid in het face-to-face gedeelte van de combibehandeling?"
"Kunt u ons hier wat meer over uw ervaringen vertellen?"
"Kunt u hier voorbeelden van geven?"
"Waar denkt u dat er verbeteringen kunnen worden aangebracht in de combi behandeling?"

De volgende vier vragen alleen stellen als de respondent geen toelichting geeft op toegankelijkheid van het online gedeelte van de combi behandeling.
"Wat is uw ervaring met betrekking tot toegankelijkheid in het online gedeelte van de combi behandeling?"
"Kunt u ons hier wat meer over uw ervaringen vertellen?"
"Kunt u hier voorbeelden van geven?"
"Waar denkt u dat er verbeteringen kunnen worden aangebracht in de combi behandeling?"

De volgende vier vragen alleen stellen als de respondent geen toelichting geeft op toegankelijkheid van het face-to-face gedeelte van de combi behandeling.
"Wat is uw ervaring met betrekking tot toegankelijkheid in het face-to-face gedeelte van de combi behandeling?"
"Kunt u ons hier wat meer over uw ervaringen vertellen?"
"Kunt u hier voorbeelden van geven?"
"Waar denkt u dat er verbeteringen kunnen worden aangebracht in de combi behandeling?"

TEVREDENHEID MET DE COMBI BEHANDELING

"Hoe is uw algemene tevredenheid over de combi behandeling?"

"Over welke onderdelen bent u minder of meer tevreden?"
"Hoe zouden we hierin verbeteringen kunnen aanbrengen volgens u?"

De volgende vier vragen alleen stellen als de respondent geen toelichting geeft op het online gedeelte van de combi behandeling.
"Hoe is uw tevredenheid over het online gedeelte van de combi behandeling?"
"Over welke onderdelen bent u het meest en minst tevreden?"
"Hoe zouden we hierin verbeteringen kunnen aanbrengen volgens u?"
„Als u mocht kiezen waar zou u dan zelf als eerste verandering in aan willen brengen? Waarom?

De volgende vragen alleen stellen als de respondent geen toelichting geeft op het face-to-face gedeelte van de combi behandeling.
"Hoe is uw tevredenheid over het face-to-face gedeelte van de combi behandeling?"
"Kunt u een voorbeeld geven van een onderdeel waar u minder tevreden over bent?"
"Hoe zouden we hierin verbeteringen kunnen aanbrengen volgens u?"
„Als u mocht kiezen waar zou u dan zelf als eerste verandering in aan willen brengen? Waarom?
"Kunt u een voorbeeld geven van een onderdeel waar u meest tevreden over bent?"

VERDELING FACE-TO-FACE EN ONLINE GEDEELTES

"Wat vindt u van de verdeling face-to-face behandelingen en online sessies?"

"Wat vond u van de tijdsverdeling?"

VOORDELEN/NADELEN

"Wat zijn voor u de belangrijkste voordelen van deze combi behandeling?
"Wat zijn voor u de belangrijkste nadelen van deze combi behandeling?"

AFSLUITING

Themalijst:

Eigen toevoeging van de patiënt	❑
Omschrijving van de behandeling	❑

EIGEN TOEVOEGING VAN DE PATIËNT

„We zijn nu met onze vragenlijst eigenlijk klaar. Is er nog iets wat uw graag wilt zeggen of toevoegen waar wij het niet over hebben gehad?“

OMSCHRIJVING COMBI BEHANDELING

“Dan wil ik u ter afsluiting graag nog een korte vragen stellen die niet zozeer over uw ervaringen gaan, maar wat meer praktisch van aard zijn.”
„We hebben het telkens over de combibehandeling, maar merken dat het soms lastig is om de behandeling goed te omschrijven. Heeft u hiervoor een tip of suggestie?

Doorvragen met b.v.

“Als u de combi behandeling in 3 woorden mag beschrijven, welke 3 woorden zouden dat dan zijn?“

AFSLUITING

- Check aan de hand van de topiclijsten of je alle vragen hebt gesteld en of je overal antwoord op hebt gekregen.
- Stel eventueel nog aanvullende vragen om de antwoorden compleet te maken.
- Kondig het einde van het gesprek aan.
- Geef de geïnterviewde de gelegenheid om vragen te stellen of om aanvullingen/ toelichtingen te geven
- Geef kort aan hoe de procedure van verwerking eruit ziet.
- Vraag de respondent om feedback over het interview: wat vond hij/zij van het interview?
- Bedank de respondent voor zijn/haar medewerking.

RAPPORT VAN DE INTERVIEWER

Onderstaande vragen graag meteen na afloop van het interview beantwoorden

1) Waren er buiten jezelf en de respondent nog andere personen aanwezig die de vragen en antwoorden konden horen?

- ❑ Niemand aanwezig (ga door naar vraag 3)
- ❑ Anderen aanwezig

2) Is de aanwezigheid van anderen volgens jou van invloed geweest op wijze waarop respondent de vragen heeft beantwoord?

- ❑ Nee/waarschijnlijk niet
- ❑ Ja/waarschijnlijk wel, namelijk

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3) Eventuele opvallende zaken voor/tijdens/na het interview

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AANVULLENDE DATA OVER PATIËNT

(UIT B.V. EERDER INGEVULDE VRAGENLIJSTEN OF DSV)

- Geslacht
- Leeftijd
- Culturele herkomst
- Burgerlijke staat
- Kinderen
- Woonsituatie
- Opleidingsniveau
- Bron van inkomst
- Dagbesteding
- Internet skills
- Fagerström
- Rookgedrag
- Rookhistorie
- Lichamelijke klachten score
- Depressie, angst, stress score
- EuroQol score

A

SUMMARY (ENGLISH)

With the advent of e-health, we are currently facing a sea change in the psychological treatment of mental health problems, as various applications of digital interventions have an impact on clinical practice, clinical services and the global spread of psychological treatments, with blended treatment - the subject of this thesis - being one of the most promising. Blended treatment started with the idea of offering both face-to-face and web-based interventions in one integrated treatment, thus overcoming their previous separation - either face-to-face or web-based - and as a result making care more customer-friendly, better quality and more targeted. This positive expectation went along with the consideration that blended treatment combines the “best of both worlds”, as the strengths of one form of treatment should compensate for the weaknesses of the other. For example, personal attention by a professional in the case of face-to-face treatment could compensate for the lack of personal contact in the case of web-based treatment. In turn, one of the main features of web-based treatment is the possibility of being available anytime and anywhere, which could bridge the intervals between sessions in face-to-face treatment.

Blending face-to-face and web-based interventions and the related question of whether this blending offers “the best of both worlds” was taken forward in this thesis in the scope of smoking cessation treatment. Smoking cessation treatment can more than double the success rates of smoking cessation attempts, thereby significantly reducing the development of smoking-related illnesses, which continue to kill more than eight million people worldwide each year. The Blended Smoking Cessation Treatment (BSCT), which is the focus of this work, was addressed by highlighting the themes of user experience, adherence and effectiveness.

The following questions were examined in detail:

- How is the patients’ user experience in a blended face-to-face and web-based smoking cessation treatment (BSCT)?
- How can adherence to BSCT be measured, how adherent are patients, and what predicts patients’ adherence?
- How is the adherence to BSCT compared to a face-to-face treatment (F2F), and what predicts adherence to BSCT compared to F2F?
- How is the adherence to both modes of delivery (Web-mode; F2F-mode) of BSCT, and what predicts adherence to both modes?
- Is BSCT at least as effective as F2F in terms of abstinence rates, and are patients more satisfied with either treatment?

To answer these questions, the results of four studies – framed by the study protocol at the beginning and a concluding general discussion – are presented in this thesis.

Chapter 2 provides the study protocol, offering an overview of the randomized controlled trial (LiveSmokefree-Study), which forms the framework of the studies in this thesis. The background, objectives and research questions are described as well as the corresponding outcomes, their measurement methods and instruments and the planned analyses. The LiveSmokefree-Study was the first study to examine the effectiveness of a blended smoking cessation treatment (BSCT) compared to purely face-to-face treatment (F2F). The study was designed as a single-center randomized controlled non-inferiority-trial with parallel groups. Patients (n=344) were randomly assigned to either the blended or the face-to-face group. Both treatments consisted of ten sessions with equal content held within 6 months. In BSCT five out of ten sessions were delivered online. Both BSCT and F2F covered the majority of behavior change techniques that are evidence-based within smoking cessation counseling. All face-to-face sessions in both treatments took place at the Outpatient Smoking Cessation Clinic of the Department of Pulmonary Medicine of Medisch Spectrum Twente hospital in Enschede (The Netherlands). The web-based interaction of BSCT – which patients will do e.g. at home – used tools of Tactus Addiction Treatment`s website http://www.rokendebaas.nl. The primary outcome parameter was biochemically validated prolonged abstinence at 15 months from the start of the smoking cessation treatment. The main highlights of the study are that BSCT was developed by a team in which relevant stakeholders actively participated, that it demonstrated high ecological validity involving the heterogeneous population of regular patients of an outpatient smoking cessation clinic, and that it included a long term biochemically validated follow-up assessment.

Chapter 3 presents a qualitative study of the user experience (UX) of the Blended Smoking Cessation Treatment (BSCT), because UX has been shown as an important factor in explaining patients' use of health care services in particular. We conducted in-depth interviews (n=10) and applied Hassenzahl's model of UX to describe the patients' UX of BSCT in routine care to address the question what positive and negative experiences patients have with BSCT in general and with the F2F sessions and the Web sessions in particular. Although the results showed that the patients experienced BSCT predominantly positively, we had the impression that BSCT's UX is characterized by a "hedonistic gap" resulting from the Web mode. While some patients felt stimulated by BSCT (BSCT stimulated to "quit smoking", "think", "dig deeper"), others reported being demotivated (BSCT "did not offer new things" or was "not interesting"). Especially for the Web sessions, most patients reported low identification ("online is not my style"). Also, the Web sessions evoked mostly negative comparisons ("Web was like handling a machine"; "bookkeeping"; "filling in tax forms"). This gap was then compensated for by the F2F-mode, giving an indication that BSCT may be "the best of both worlds", as the strength of one mode (in this case the stronger hedonistic aspects of the F2F-mode) could compensate for the weaknesses of the other mode. Even though it is not yet clear how relevant hedonistic aspects were, as BSCT was generally experienced positively, hedonistic aspects such as fun, enjoyment, pleasure and aesthetics seem to be a good opportunity to further develop BSCT.

Chapter 4 begins the study of adherence, since adherence is an indicator of the acceptance of a treatment and a primary determinant of its effectiveness. In the first study on this topic, we addressed the measurement, levels and predictors of adherence in BSCT by quantitatively analyzing the patients' face-to-face and web-based activities during treatment. Since blended treatment was still a relatively new field, we first explored how adherence could be measured in this area. We designed and compared two methods of measuring adherence to BSCT: a complex one, in which the treatment activities of BSCT patients were accurately recorded, and an efficient one, in which only the treatment time was calculated as an indicator of adherence; and we determined the advantages and disadvantages of both methods. Using the first method (activity-based), which we applied to a sample (n=75) of BSCT patients, we found that adherence to BSCT was rather low, and we found rather social predictors of higher adherence (living with a partner; having few smoking friends).
Chapter 5 continues the discussion of adherence by comparing the adherence and the predictors of adherence in BSCT with those of F2F. In addition, we looked at both treatment modes of BSCT in detail and compared the adherence and the predictors of adherence in the face-to-face mode of BSCT with its Web mode. Interestingly, when using the second method (time-based) for measuring adherence, which we applied to a larger sample (n=292) to compare BSCT to F2F, the adherence was rather high, and this equally in both treatments. And we found other predictors of higher adherence (higher age for BSCT and F2F; stronger social support only for F2F). The seemingly contradictory results on adherence levels could be explained by differences in the measurement procedures and differences in the analysis, which made the activity-based measurement procedure appear more specific and the time-based procedure more sensitive.

We also used the time-based method to compare the two treatment modes (F2F-mode vs. Web-mode) of BSCT and found that BSCT patients adhered more to F2F-mode than to Web-mode since they spent twice as much time in F2F-mode as in Web-mode. Furthermore, the predictors differed between the two modes of BSCT: to be living without children predicted a higher adherence to the F2F mode, while a combination of an extrinsic motivation to quit, a less negative attitude towards quitting and less health complaints did this for the Web mode.

Chapter 6 addresses the effectiveness of BSCT. We compared the abstinence rates of BSCT with a comparable face-to-face treatment to find out if the new blended treatment was non-inferior to the traditional face-to-face treatment. Furthermore, we compared the patients' satisfaction with both treatments. Contrary to our expectations, we did not find any evidence

of non-inferiority of BSCT to F2F. On the contrary, in the most important measurement - cotinine-validated point prevalence abstinence - the intention-to-treat analysis showed significantly lower abstinence rates of BSCT (4.8%) compared to F2F (17.5%). Based on a Bayse factor calculation, we interpreted this as very strong evidence for the inferiority of BSCT. However, this result should be considered with caution, as unfortunately only very few samples were available to us for analysis, so that we must assume a confounding due to missing data. This assumption is also supported by the fact that this significant inferiority was not reflected in the CO measurements, nor in two of the four self-reported abstinence measurements. However, it must also be made clear that although we did not find inferiority of the BSCT in all measurement points, conversely, we did not find non-inferiority or even superiority of the BSCT in any measurement. We must therefore assume that BSCT was inferior. Interestingly, however, this inferiority was not found in patient satisfaction, which was also evaluated in this interim analysis. Both treatment groups rated their own treatment results as well as the treatment and counsellors equally good.

Chapter 7 presents the general discussion in which we summarize the results of the sub studies, make methodological considerations, consider implications for clinical practice and further research, and return to the question whether blending offers “the best of both worlds”. Looking at the results of the above-mentioned sub-studies, a mixed picture emerged. We have found indications that in BSCT the strengths of one approach outweigh the weaknesses of the other. But this only went in one direction: the strengths of the F2F-mode compensated for the weaknesses of the Web-mode, as was shown in the user experience description and in the analysis of adherence to BSCT. It seemed that the web-based part of BSCT could not bring any strengths into the interaction of the two treatment modes. If one then considers that BSCT leads to lower abstinence rates - i.e. is less effective - compared to F2F, while adherence, measured as treatment time, was the same for both treatments, BSCT appears less efficient. This would mean that the expected valuable further development would therefore not be experienced with BSCT.

We have approached the idea of a blended treatment with positive expectations, as we believed that this form of treatment fits better to the current lifestyle of patients and professionals. If we now look at the results of the studies, their methodological consideration, and their implications, we find that not every realization of blended treatment automatically is also an improvement. With this realization - Blended Smoking Cessation Treatment - it seems that the expected potential of blending web-based and face-to-face interventions has not been unleashed. This research project, which provided many detailed findings on the subject of blended treatment, is thus sharpening the eye for a better type of blended treatment in the future, so that the potential of this current and innovative approach, which is expected to combine the “best of both worlds”, will be realized.

SAMENVATTING (DUTCH)

Met de komst van e-health worden we momenteel geconfronteerd met een ingrijpende verandering in de psychologische behandeling van geestelijke gezondheidsproblemen, aangezien verschillende toepassingen van digitale interventies een impact hebben op de klinische praktijk, de klinische dienstverlening en de wereldwijde verspreiding van psychologische behandelingen, waarbij blended treatment - het onderwerp van deze dissertatie - een van de meest veelbelovende is. Blended treatment begon met het idee om zowel face-to-face als web-based interventies aan te bieden in één geïntegreerde behandeling, waardoor de eerdere scheiding - face-to-face of web-based - wordt opgeheven en de zorg daardoor klantvriendelijker, kwalitatief beter en gerichter wordt. Deze positieve verwachting ging gepaard met de overweging dat een blended behandeling het “beste van twee werelden” combineert, aangezien de sterke punten van de ene vorm van behandeling de zwakke punten van de andere moeten compenseren. Zo kan persoonlijke aandacht van een professional in het geval van een face-to-face behandeling het gebrek aan persoonlijk contact in het geval van een web-based behandeling compenseren. Een van de belangrijkste kenmerken van een web gebaseerde behandeling is dan weer de mogelijkheid om altijd en overal beschikbaar te zijn, waardoor de intervallen tussen de sessies in de face-to-face-behandeling kunnen worden overbrugd.

Het blenden van face-to-face en web-based interventies en de daarmee samenhangende vraag of dit blenden “het beste van twee werelden” biedt, werd in deze dissertatie in het kader van de stoppen met roken behandeling naar voren gebracht. De behandeling bij het stoppen met roken kan het succespercentage van de pogingen om te stoppen met roken meer dan verdubbelen, waardoor de ontwikkeling van rook gerelateerde ziekten, die wereldwijd nog steeds meer dan acht miljoen mensen per jaar doden, aanzienlijk kan worden teruggedrongen. De BSCT (Blended Smoking Cessation Treatment), die de focus van dit werk vormt, werd aangepakt door de thema’s van de gebruikerservaring, de adherentie en de effectiviteit te benadrukken.

De volgende vragen werden in detail onderzocht:

- Hoe is de gebruikerservaring van de patiënten bij een blended face-to-face en web-based stoppen met roken behandeling (BSCT)?
- Hoe kan de adherentie van de BSCT worden gemeten, hoe hecht de patiënt zich aan de BSCT en wat voorspelt de patiënt dat hij zich aan de BSCT houdt?
- Hoe is de adherentie aan BSCT vergeleken met een face-to-face behandeling (F2F), en wat voorspelt de adherentie aan BSCT vergeleken met F2F?
- Hoe is de adherentie aan beide manieren van toediening (Web-mode; F2F-mode) van BSCT, en wat voorspelt de adherentie aan beide modi?
- Is BSCT minstens zo effectief als F2F in termen van stoppen met roken, en zijn patiënten meer tevreden met een van de twee behandelingen?

Om deze vragen te beantwoorden, worden de resultaten van vier studies - omlijst door het onderzoeksprotocol aan het begin en een afsluitende algemene discussie - in dit proefschrift gepresenteerd.

Hoofdstuk 2 geeft het onderzoeksprotocol, dat een overzicht biedt van de gerandomiseerde gecontroleerde studie (LiveSmokefree-Study), die het kader vormt van de studies in dit proefschrift. De achtergrond, doelstellingen en onderzoeksvragen worden beschreven, evenals de bijbehorende uitkomsten, hun meetmethoden en instrumenten en de geplande analyses. De LiveSmokefree-Studie was de eerste studie die de effectiviteit van een blended smoking staking behandeling (BSCT) onderzocht in vergelijking met een zuivere face-to-face behandeling (F2F). De studie werd ontworpen als een single-center gerandomiseerde gecontroleerde niet-inferioriteitsproef met parallelle groep. De patiënten (n = 344) werden willekeurig toegewezen aan de blended of de face-to-face groep. Beide behandelingen bestonden uit tien sessies met gelijke inhoud, gehouden binnen 6 maanden. In BSCT werden vijf van de tien sessies online gegeven. Zowel BSCT als F2F behandelden de meerderheid van de technieken voor gedragsverandering die evidence-based zijn binnen de begeleiding bij het stoppen met roken. Alle face-to-face sessies in beide behandelingen vonden plaats in de polikliniek voor stoppen met roken van de afdeling Longgeneeskunde van het Medisch Spectrum Twente ziekenhuis in Enschede (Nederland). De web-based interactie van BSCT - die patiënten bijvoorbeeld thuis zullen doen - maakte gebruik van tools van de website http://www.rokendebaas.nl van Tactus Verslavingszorg. De primaire uitkomstparameter was biochemisch gevalideerde langdurige abstinentie op 15 maanden vanaf het begin van de rookstopbehandeling. De belangrijkste hoogtepunten van het onderzoek zijn dat BSCT werd ontwikkeld door een team waarin alle relevante belanghebbenden actief deelnamen, dat het een hoge ecologische validiteit aantoonde met betrekking tot de heterogene populatie van reguliere patiënten van een polikliniek voor stoppen met roken, en dat het een lange termijn biochemisch gevalideerde follow-up beoordeling omvatte.

Hoofdstuk 3 presenteert een kwalitatieve studie van de gebruikerservaring (user experience, UX) van de Blended Smoking Cessation Treatment (BSCT), omdat UX is aangetoond als een belangrijke factor in het verklaren van het gebruik van gezondheidsdiensten door patiënten in het bijzonder. We voerden diepte-interviews uit (n=10) en pasten Hassenzahl's model van UX toe om de UX van de patiënten van BSCT te beschrijven in de routinezorg om de vraag te beantwoorden welke positieve en negatieve ervaringen patiënten hebben met BSCT in het algemeen en met de F2F-sessies en de web sessies in het bijzonder. Hoewel de resultaten lieten zien dat de patiënten BSCT overwegend positief ervaren, hadden we de indruk dat de UX van BSCT wordt gekenmerkt door een "hedonistic gap" als gevolg van de web modus. Terwijl sommige patiënten zich gestimuleerd voelden door BSCT (BSCT stimuleerde om "te stoppen met roken", "te denken", "dieper te graven"), meldden anderen dat ze gedemotiveerd waren (BSCT "bood geen nieuwe dingen aan" of was "niet interessant"). Vooral voor de web sessies meldden de meeste patiënten een lage identificatie ("online is niet mijn stijl"). Ook riepen de web sessies meestal negatieve vergelijkingen op ("Web was als het omgaan met een machine"; "boekhouding"; "het invullen van belastingformulieren"). Dit gat werd vervolgens gecompenseerd door de F2F-modus, wat een indicatie geeft dat BSCT "het beste van twee werelden" kan zijn, aangezien de kracht van de ene modus (in dit geval de sterkere hedonistische aspecten van de F2F-modus) de zwakheden van de andere modus zou kunnen compenseren. Hoewel het nog niet duidelijk is hoe relevant hedonistische aspecten waren, aangezien BSCT over het algemeen positief werd ervaren, lijken hedonistische aspecten zoals plezier, genot en esthetiek een goede gelegenheid te zijn om BSCT verder te ontwikkelen.

In hoofdstuk 4 wordt een begin gemaakt met het onderzoek naar adherentie, aangezien adherentie een indicator is voor de acceptatie van een behandeling en een primaire determinant voor de effectiviteit ervan. In de eerste studie over dit onderwerp hebben we de meting, niveaus en voorspellers van adherentie in BSCT behandeld door de face-to-face en web-based activiteiten van de patiënten tijdens de behandeling kwantitatief te analyseren. Aangezien de blended behandeling nog een relatief nieuw gebied was, hebben we eerst onderzocht hoe de adherentie op dit gebied kon worden gemeten. We ontwierpen en vergeleken twee methoden om de adherentie van BSCT te meten: een complexe methode, waarbij de behandelingsactiviteiten van BSCT-patiënten nauwkeurig werden geregistreerd, en een efficiënte methode, waarbij alleen de behandelingstijd werd berekend als indicator voor adherentie; en we bepaalden de voor- en nadelen van beide methoden. Met de eerste methode (activity-based), die we toepasten op een steekproef (n=75) van BSCT-patiënten, vonden we dat de adherentie aan BSCT vrij laag was, en we vonden vrij sociale voorspellers van een hogere adherentie (leven met een partner; weinig rokende vrienden hebben).

In hoofdstuk 5 wordt de discussie over adherentie voortgezet door de adherentie en de prediktoren van adherentie in BSCT te vergelijken met die van F2F. Daarnaast hebben we beide behandelmodi van BSCT in detail bekeken en de adherentie en de prediktoren van adherentie in de face-to-face modus van BSCT vergeleken met de web modus. Interessant is dat bij gebruik van de tweede methode (time-based) voor het meten van de adherentie, die we hebben toegepast op een grotere steekproef (n=292) om BSCT te vergelijken met F2F, de adherentie vrij hoog was, en dit gelijkelijk in beide behandelingen. En we vonden andere voorspellers van hogere adherentie (hogere leeftijd voor BSCT en F2F; sterkere sociale steun alleen voor F2F). De schijnbaar tegenstrijdige resultaten op het gebied van adherentie niveaus konden worden verklaard door verschillen in de meetprocedures

en verschillen in de analyse, waardoor de op activiteiten gebaseerde meetprocedure specifieker leek en de op tijd gebaseerde procedure gevoeliger.

We gebruikten ook de tijd gebaseerde methode om de twee behandelingsmodi (F2F-mode vs. Web-mode) van BSCT te vergelijken en vonden dat BSCT-patiënten zich meer aan de F2F-mode hielden dan aan de Web-mode omdat ze twee keer zoveel tijd in de F2F-mode doorbrachten als in de Web-mode. Bovendien verschilden de voorspellers tussen de twee modi van BSCT: leven zonder kinderen voorspelde een hogere adherentie aan de F2F-mode, terwijl een combinatie van een extrinsieke motivatie om te stoppen, een minder negatieve houding ten opzichte van stoppen en minder gezondheidsklachten dit deed voor de Web-mode.

Hoofdstuk 6 gaat in op de effectiviteit van BSCT. We hebben de abstinentiecijfers van BSCT vergeleken met een vergelijkbare face-to-face behandeling om na te gaan of de nieuwe blended behandeling niet inferieur is aan de traditionele face-to-face behandeling. Verder hebben we de tevredenheid van de patiënten met beide behandelingen vergeleken. In tegenstelling tot onze verwachtingen vonden we geen bewijs van niet-inferioriteit van BSCT naar F2F. Integendeel, in de belangrijkste meting - cotinine-validated point prevalence abstinence - liet de intention-to-treat-analyse significant lagere onthoudingspercentages van BSCT (4,8%) zien in vergelijking met F2F (17,5%). Op basis van een Bayes factorberekening interpreteerden we dit als zeer sterk bewijs voor de inferioriteit van BSCT. Dit resultaat moet echter met de nodige voorzichtigheid worden bekeken, aangezien er helaas slechts zeer weinig monsters voor analyse beschikbaar waren, zodat we moeten uitgaan van een confounding als gevolg van ontbrekende gegevens. Deze veronderstelling wordt ook ondersteund door het feit dat deze significante inferioriteit niet werd weerspiegeld in de CO-metingen, noch in twee van de vier zelf gerapporteerde onthoudingsmetingen. Het moet echter ook duidelijk zijn dat, hoewel we niet op alle meetpunten een inferioriteit van de BSCT hebben gevonden, we in geen enkele meting een niet-inferioriteit of zelfs maar een superioriteit van de BSCT hebben gevonden. We moeten er dus van uitgaan dat de BSCT inferieur was. Interessant is echter dat deze inferioriteit niet werd gevonden in de patiënttevredenheid, die ook in deze tussentijdse analyse werd geëvalueerd. Beide behandelingsgroepen beoordeelden zowel de eigen behandelresultaten als de behandeling en de begeleiders even goed.

Hoofdstuk 7 presenteert de algemene discussie waarin we de resultaten van de deelonderzoeken samenvatten, methodologische afwegingen maken, implicaties voor de klinische praktijk en verder onderzoek overwegen en terugkomen op de vraag of blending ‘the best of both worlds’ biedt. Als we de resultaten van de bovengenoemde deelonderzoeken bekijken, ontstaat een gemengd beeld. We hebben aanwijzingen

gevonden dat in BSCT de sterke punten van de ene benadering opwegen tegen de zwakke punten van de andere. Maar dit ging slechts in één richting: de sterke punten van de F2F-modus compenseerden de zwakke punten van de web modus, zoals bleek uit de beschrijving van de gebruikerservaring en uit de analyse van de naleving van BSCT. Het leek erop dat het web-gebaseerde deel van BSCT geen sterktes in de interactie van de twee behandelmodi kon brengen. Als men dan bedenkt dat BSCT leidt tot lagere onthoudingscijfers - d.w.z. minder effectief is - in vergelijking met F2F, terwijl de adherentie, gemeten als behandelingsduur, voor beide behandelingen gelijk was, lijkt BSCT minder efficiënt te zijn. Dit zou betekenen dat de verwachte waardevolle verdere ontwikkeling niet wordt ervaren met BSCT.

We hebben het idee van een gemengde behandeling benaderd met positieve verwachtingen, omdat we dachten dat deze vorm van behandeling beter past bij de huidige levensstijl van patiënten en professionals. Als we nu kijken naar de resultaten van de onderzoeken, hun methodologische afweging en hun implicaties, dan zien we dat niet elke realisatie van een blended behandeling automatisch ook een verbetering is. Met deze realisatie - Blended Smoking Cessation Treatment - lijkt het verwachte potentieel van het mengen van web-based en face-to-face interventies niet te zijn gelukt. Dit onderzoeksproject, dat veel gedetailleerde bevindingen over het onderwerp blended treatment heeft opgeleverd, scherpt zo de ogen voor een beter type blended behandeling in de toekomst, zodat de potentie van deze huidige en innovatieve aanpak, die naar verwachting het “beste van twee werelden” zal combineren, wordt gerealiseerd.

ZUSAMMENFASSUNG (DEUTSCH)

Mit dem Aufkommen von E-Health stehen wir derzeit vor einem tiefgreifenden Wandel in der psychologischen Behandlung von psychischen Gesundheitsproblemen, da verschiedene Anwendungen digitaler Interventionen Auswirkungen auf die klinische Praxis, die klinischen Dienste und die weltweite Verbreitung psychologischer Behandlungen haben, wobei Blended Treatment - das Thema dieser Arbeit - eine der vielversprechendsten ist. Blended Treatment begann mit der Idee, sowohl Face-to-Face- als auch webbasierte Interventionen in einer integrierten Behandlung anzubieten und so deren bisherige Trennung - entweder Face-to-Face oder webbasiert - zu überwinden und als Ergebnis die Versorgung kundenfreundlicher, qualitativ besser und zielgerichteter zu gestalten. Diese positive Erwartung ging einher mit der Idee, dass Blended Treatment das „Beste aus beiden Welten“ kombiniert, da die Stärken der einen Behandlungsform die Schwächen der anderen ausgleichen sollten. So könnte z.B. die persönliche Betreuung durch eine Fachkraft im Falle einer Behandlung von Angesicht zu Angesicht den Mangel an persönlichem Kontakt im Falle einer webbasierten Behandlung ausgleichen. Eines der Hauptmerkmale der webbasierten Behandlung wiederum ist die Möglichkeit, jederzeit und überall verfügbar zu sein, was bei der Face-to-Face-Behandlung die Intervalle zwischen den Sitzungen überbrücken könnte. Blending von Face-to-Face- und webbasierten Interventionen und die damit verbundene Frage, ob diese Vermischung „das Beste aus beiden Welten“ bietet, wurde in dieser Arbeit im Rahmen der Raucherentwöhnungsbehandlung aufgegriffen. Eine Raucherentwöhnungsbehandlung kann die Erfolgsraten von Raucherentwöhnungsversuchen mehr als verdoppeln und damit die Entwicklung rauchbedingter Erkrankungen, an denen nach wie vor jedes Jahr weltweit mehr als acht Millionen Menschen sterben, deutlich verringern. Blended Treatment zur Raucherentwöhnung (Blended Smoking Cessation Treatment, BSCT), die im Mittelpunkt dieser Arbeit steht, wurde unter Hervorhebung der Themen Benutzererfahrung, Adhärenz und Wirksamkeit behandelt.

Die folgenden Fragen wurden im Einzelnen untersucht:

- Wie ist die Benutzererfahrung der Patienten bei einer kombinierten face-to-face- und webbasierten Raucherentwöhnungsbehandlung (BSCT)?
- Wie kann die Adhärenz der BSCT gemessen werden, wie adhärent sind die Patienten und was sagt die Adhärenz der Patienten voraus?
- Wie ist die Adhärenz zu BSCT im Vergleich zu einer Face-to-Face-Behandlung (F2F), und was sagt die Adhärenz zu BSCT im Vergleich zu F2F voraus?
- Wie ist die Adhärenz bei beiden Verabreichungsformen (Web-Modus; F2F-Modus) von BSCT, und was sagt die Adhärenz bei beiden Modi voraus?
- Ist BSCT in Bezug auf die Abstinenzraten mindestens so wirksam wie F2F, und sind die Patienten mit einer der beiden Behandlungsmethoden zufriedener?

Um diese Fragen zu beantworten, werden in dieser Arbeit die Ergebnisse von vier Studien

- eingerahmt durch das Studienprotokoll zu Beginn und eine abschließende allgemeine Diskussion - vorgestellt.

Kapitel 2 enthält das Studienprotokoll und bietet einen Überblick über die randomisierte kontrollierte Studie (LiveSmokefree-Study), die den Rahmen der Studien in dieser Arbeit bildet. Die Hintergründe, Ziele und Forschungsfragen werden ebenso beschrieben wie die entsprechenden Ergebnisse, ihre Messmethoden und -instrumente und die geplanten Analysen. Die LiveSmokefree-Studie war die erste Studie, die die Wirksamkeit einer gemischten Raucherentwöhnungsbehandlung (BSCT) im Vergleich zu einer reinen Face-to-Face-Behandlung (F2F) untersuchte. Die Studie war als randomisierte, kontrollierte Nicht-Unterlegenheitsstudie mit Parallelgruppe konzipiert, die in einem einzigen Zentrum durchgeführt wurde. Die Patienten (n = 344) wurden randomisiert entweder der Blended oder der Face-to-Face-Gruppe zugeordnet. Beide Behandlungen bestanden aus zehn Sitzungen mit gleichem Inhalt, die innerhalb von 6 Monaten durchgeführt wurden. Bei der BSCT wurden fünf von zehn Sitzungen online durchgeführt. Sowohl BSCT als auch F2F deckten die Mehrzahl der Verhaltensänderungstechniken ab, die im Rahmen der Raucherentwöhnungsberatung evidenzbasiert sind. Alle persönlichen Sitzungen in beiden Behandlungen fanden in der Ambulanten Raucherentwöhnungsklinik der Abteilung für Lungenheilkunde des Krankenhauses Medisch Spectrum Twente in Enschede (Niederlande) statt. Bei der webbasierten Interaktion der BSCT - die die Patienten z.B. zu Hause durchführen werden - wurden Instrumente der Website http://www.rokendebaas.nl von Tactus Verslavingszorg (Enschede/Niederlande) verwendet. Der primäre Ergebnisparameter war eine biochemisch validierte verlängerte Abstinenz nach 15 Monaten ab Beginn der Raucherentwöhnungsbehandlung. Die wichtigsten Highlights der Studie sind, dass die BSCT von einem Team entwickelt wurde, an dem viele relevante Stakeholder aktiv beteiligt waren, dass sie eine hohe ökologische Validität unter Einbeziehung der heterogenen Population der regulären Patienten einer ambulanten Raucherentwöhnungsklinik zeigte und dass sie eine biochemisch validierte Langzeit-Folgebeurteilung beinhaltete.

In Kapitel 3 wird eine qualitative Studie über die Benutzererfahrung (UX) mit dem Blended Smoking Cessation Treatment (BSCT) vorgestellt, da sich UX als ein wichtiger Faktor erwiesen hat, um die Inanspruchnahme von Gesundheitsdiensten durch Patienten im Besonderen zu erklären. Wir führten Tiefeninterviews (n=10) durch und wandten das UX-Modell von Hassenzahl an, um die UX der BSCT-Patienten in der Routineversorgung zu beschreiben und damit der Frage nachzugehen, welche positiven und negativen Erfahrungen Patienten mit BSCT im Allgemeinen und mit den F2F-Sitzungen und den Web-Sitzungen im Besonderen machen. Obwohl die Ergebnisse zeigten, dass die Patienten BSCT überwiegend positiv erlebten, hatten wir den Eindruck, dass die UX von BSCT durch ein „hedonistic gap“ gekennzeichnet ist, die aus dem Web-Modus resultiert. Während sich einige Patienten durch die BSCT stimuliert fühlten (BSCT stimuliert zu „Raucherentwöhnung“, „Nachdenken“, „tiefer graben“), gaben andere an, demotiviert zu sein (BSCT „bot nichts Neues“ oder war „nicht interessant“). Insbesondere bei den Web-Sitzungen berichteten die meisten Patienten über eine geringe Identifikation („online ist nicht mein Stil“). Auch riefen die Web-Sitzungen meist negative Vergleiche hervor („Web war wie der Umgang mit einer Maschine“; „Buchhaltung“; „Ausfüllen von Steuerformularen“). Diese Lücke wurde dann durch den F2F-Modus kompensiert, was darauf hindeutet, dass BSCT „das Beste aus beiden Welten“ sein könnte, da die Stärke des einen Modus (in diesem Fall die stärkeren hedonistischen Aspekte des F2F-Modus) die Schwächen des anderen Modus ausgleichen könnte. Auch wenn noch nicht klar ist, wie relevant hedonistische Aspekte waren, da BSCT allgemein positiv erlebt wurde, scheinen hedonistische Aspekte wie Spaß, Genuss, Vergnügen und Ästhetik eine gute Gelegenheit zu sein, BSCT weiterzuentwickeln.

Kapitel 4 beginnt mit der Untersuchung der Adhärenz, da die Adhärenz ein Indikator für die Akzeptanz einer Behandlung und ein primärer Bestimmungsfaktor für ihre Wirksamkeit ist. In der ersten Studie zu diesem Thema befassten wir uns mit der Messung, dem Niveau und den Prädiktoren der Adhärenz bei der BSCT, indem wir die persönlichen und webbasierten Aktivitäten der Patienten während der Behandlung quantitativ analysierten. Da blended treatment noch ein relativ neues Gebiet war, untersuchten wir zunächst, wie die Adhärenz in diesem Bereich gemessen werden kann. Wir entwarfen und verglichen zwei Methoden zur Messung der Adhärenz bei BSCT: eine komplexe, bei der die Behandlungsaktivitäten von BSCT-Patienten genau erfasst wurden, und eine effiziente, bei der nur die Behandlungszeit als Indikator für die Adhärenz berechnet wurde; und wir ermittelten die Vor- und Nachteile beider Methoden. Mit der ersten Methode (aktivitätsbasiert), die wir auf eine Stichprobe (n=75) von BSCT-Patienten anwandten, stellten wir fest, dass die Adhärenz bei BSCT eher gering war, und wir fanden eher soziale Prädiktoren für eine höhere Adhärenz (Zusammenleben mit einem Partner; wenig rauchende Freunde).

Kapitel 5 setzt die Diskussion über die Adhärenz fort, indem es die Einhaltung und die Prädiktoren der Einhaltung von BSCT mit denen von F2F vergleicht. Darüber hinaus haben wir beide Behandlungsmodi der BSCT im Detail betrachtet und die Adhärenz und die Prädiktoren der Adhärenz im Face-to-Face-Modus der BSCT mit ihrem Web-Modus verglichen. Interessanterweise war bei Verwendung der zweiten Methode (zeitbasiert) zur Messung der Adhärenz, die wir auf eine größere Stichprobe (n=292) anwandten, um BSCT mit F2F zu vergleichen, die Adhärenz ziemlich hoch, und zwar bei beiden Behandlungen gleichermaßen. Und wir fanden weitere Prädiktoren für eine höhere Adhärenz (höheres Alter für BSCT und F2F; stärkere soziale Unterstützung nur für F2F). Die scheinbar widersprüchlichen Ergebnisse bezüglich der Adhärenzniveaus ließen sich durch Unterschiede in den Messverfahren und Unterschiede in der Analyse erklären, die

das aktivitätsbasierte Messverfahren spezifischer und das zeitbasierte Verfahren sensibler erscheinen ließen.

Wir verwendeten die zeitbasierte Methode auch zum Vergleich der beiden Behandlungsmodi (F2F-Modus vs. Web-Modus) von BSCT und fanden heraus, dass BSCT-Patienten im F2F-Modus adhärenter als im Web-Modus waren, da sie doppelt so viel Zeit im F2F-Modus wie im Web-Modus verbrachten. Darüber hinaus unterschieden sich die Prädiktoren zwischen den beiden Modi von BSCT: Ein Leben ohne Kinder sagte eine höhere Adhärenz zum F2F-Modus voraus, während eine Kombination aus einer extrinsischen Motivation zum Aufhören, einer weniger negativen Einstellung zum Aufhören und weniger gesundheitlichen Beschwerden dies für den Web-Modus bewirkte.

Kapitel 6 befasst sich mit der Wirksamkeit der BSCT. Wir verglichen die Abstinenzraten der BSCT mit einer vergleichbaren Face-to-Face-Behandlung, um herauszufinden, ob die neue Mischbehandlung der traditionellen Face-to-Face-Behandlung nicht unterlegen war. Darüber hinaus verglichen wir die Zufriedenheit der Patienten mit beiden Behandlungen. Entgegen unseren Erwartungen fanden wir keine Hinweise auf eine Nichtunterlegenheit der BSCT gegenüber F2F. Im Gegenteil, in der wichtigsten Messung - der Cotinin-validierten Punktprävalenz-Abstinenz - zeigte die Intention-to-treat-Analyse signifikant niedrigere Abstinenzraten bei BSCT (4,8%) im Vergleich zu F2F (17,5%). Basierend auf einer Bayes-Faktor-Berechnung interpretierten wir dies als sehr starken Beleg für die Unterlegenheit von BSCT. Dieses Ergebnis ist jedoch mit Vorsicht zu betrachten, da uns leider nur sehr wenige Proben zur Analyse zur Verfügung standen, so dass wir aufgrund fehlender Daten ein Confounding erwarten müssen. Diese Annahme wird auch dadurch gestützt, dass sich diese signifikante Unterlegenheit weder in den CO-Messungen noch in zwei der vier selbstberichteten Abstinenzmessungen widerspiegelte. Es muss aber auch klargestellt werden, dass wir zwar nicht in allen Messpunkten eine Unterlegenheit von BSCT fanden, aber umgekehrt in keiner Messung eine Nichtunterlegenheit oder gar Überlegenheit von BSCT gefunden haben. Wir müssen also davon ausgehen, dass BSCT unterlegen war. Interessanterweise fand sich diese Unterlegenheit jedoch nicht bei der Patientenzufriedenheit, die in dieser Zwischenanalyse ebenfalls ausgewertet wurde. Beide Behandlungsgruppen bewerteten sowohl ihre eigenen Behandlungsergebnisse als auch die Behandlung und die Berater gleich gut.

Kapitel 7 stellt die allgemeine Diskussion dar, in der wir die Ergebnisse der Teilstudien zusammenfassen, methodische Überlegungen anstellen, Implikationen für die klinische Praxis und die weitere Forschung berücksichtigen und auf die Frage zurückkommen, ob das Mischen „das Beste aus beiden Welten“ bietet. Betrachtet man die Ergebnisse der oben erwähnten Teilstudien, so ergibt sich ein gemischtes Bild. Wir haben Hinweise darauf gefunden, dass bei der BSCT die Stärken des einen Ansatzes die Schwächen des anderen überwiegen. Dies ging jedoch nur in eine Richtung: Die Stärken des F2F-Modus kompensierten die Schwächen des Web-Modus, wie die Beschreibung der Benutzererfahrung und die Analyse der Adhärenz von BSCT zeigten. Es schien, dass der webbasierte Teil der BSCT keine Stärken in die Interaktion der beiden Behandlungsmodi einbringen konnte. Wenn man dann bedenkt, dass BSCT im Vergleich zu F2F zu niedrigeren Abstinenzraten führt - d.h. weniger effektiv ist -, während die Adhärenz, gemessen als Behandlungszeit, bei beiden Behandlungen gleich war, erscheint BSCT weniger effizient. Dies würde bedeuten, dass die erwartete wertvolle Weiterentwicklung bei BSCT daher nicht eintreten würde.

Wir haben uns der Idee von blended treatment mit positiven Erwartungen genähert, da wir der Meinung waren, dass diese Behandlungsform besser zum gegenwärtigen Lebensstil von Patienten und Fachkräften passt. Wenn wir uns nun die Ergebnisse der Studien, ihre methodische Betrachtung und ihre Implikationen ansehen, stellen wir fest, dass nicht jede Realisierung einer Mischbehandlung automatisch auch eine Verbesserung darstellt. Mit dieser Innovation - Blended Smoking Cessation Treatment - scheint es, dass das erwartete Potenzial der Mischung von webbasierten und Face-to-Face-Interventionen nicht freigesetzt worden ist. Dieses Forschungsprojekt, das viele detaillierte Erkenntnisse zum Thema Blended Treatment lieferte, schärft somit den Blick für eine bessere Art von Blended Treatment in der Zukunft, so dass das Potenzial dieses aktuellen und innovativen Ansatzes, von dem erwartet wird, dass er das „Beste aus beiden Welten“ kombiniert, realisiert wird.

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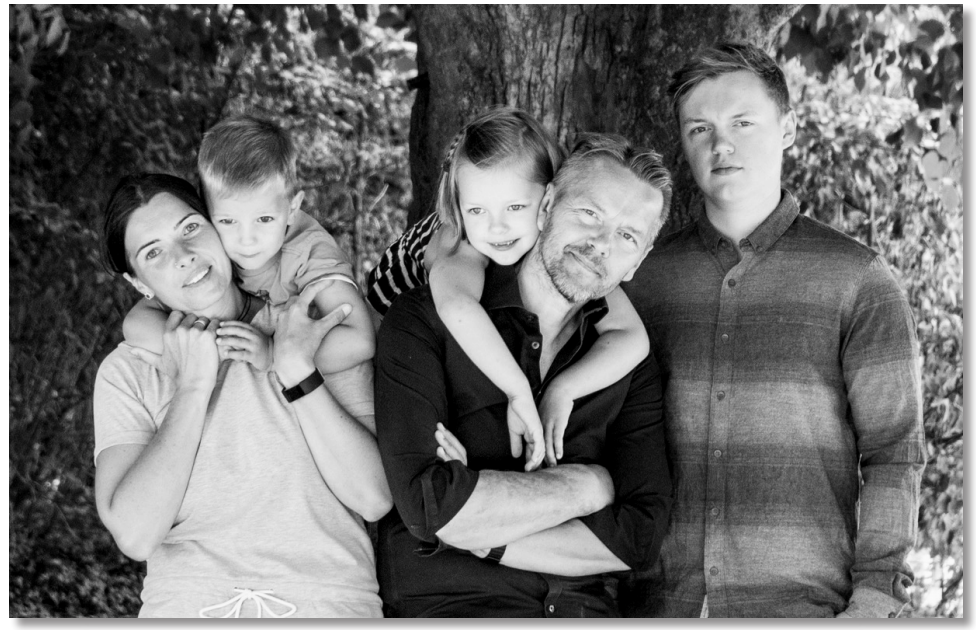
Lutz Siemer



CURRICULUM VITAE

Lutz Siemer (born 1968 in Dannenberg/Germany) completed his studies of Critical Psychology at the Psychologisches Institut of the Free University of Berlin in 1995 with a focus on clinical psychology. At the same time, he trained as a natural health practitioner and opened his own practice in the Rheine, Germany, in 1997. From 2000 to 2006 he was co-founder and manager of the Naturheilzentrum Rheine and the health event platform Forum Naturheilkunde.

Parallel to his practice activities, he was active in adult education on medical and psychological topics and taught vocational training in the field of elderly care. In addition, he was and still is active in the training and continuing education of natural health practitioners and offers continuing education for professionals in youth care.

Since 2005 he has been a lecturer at the School of Social Work at the Saxion University of Applied Sciences in Enschede, the Netherlands, where he mainly teaches empirical social research and deals with the topic of digitization in social work. From 2008 to 2010 he was a member of the research group Community Care & Youth and from 2014 to 2019 a member of the research group Technology, Health & Care.

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PUBLICATIONS AND PRESENTATIONS

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- Homepage: https://lutzsiemer.de

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PRESENTATIONS, POSTERS AND OTHER CONTRIBUTIONS TO CONFERENCES, SEMINARS AND THE LIKE

sozial.digital - Hilfe! Wir digitalisieren uns. Arlt Symposium 2020, online, bazaar.digital „Digital Youth Work – Wie macht man die Soziale Arbeit fit für digitale Jugend?“

sozial.digital - Hilfe! Wir digitalisieren uns. Arlt Symposium 2020, online, debate.digital „Integrierte Online- und Offline-Behandlung (Blended Treatment) – das Beste aus beiden Welten?“

ERS European Respiratory Society International Congress, 2020, virtual, presentation “Outpatient smoking cessation: preliminary findings of a non-inferiority RCT comparing blended with face-to-face delivery mode”

Supporting Health by Tech X, Enschede, 2020 (did not take place because of COVID-19 pandemic), oral presentation “Adherence to Smoking Cessation Treatment and predictors of adherence: Comparing Blended Treatment with Face-To-Face Treatment”

Supporting Health by Tech X, Enschede, 2020 (did not take place because of COVID-19 pandemic), oral presentation “Outpatient smoking cessation: Preliminary findings of a non-inferiority RCT comparing blended with face-to-face delivery mode”

Bilim Teacher Academy Live Broadcast, 2020, Osmaniye/Turkey, “Tips for Online Youth Work”

Academie Mens & Maatschappij Agora – Tag, Saxion University of Applied Sciences, 2020, Enschede/The Netherlands, workshop „Social Work 2.0 ... 4.0 ...? Was bedeutest der Megatrend Digitalisierung für die Soziale Arbeit?“

NNvT Nederlands Netwerk voor Tabaksonderzoek Congress, 2020, Utrecht/The Netherlands, oral presentation “Adherentie aan een blended stoppen met roken behandeling en voorspellers van adherentie – Vergelijk van blended face-to-face en web-gebaseerd behandeling met face-to-face behandeling”

E-health en innovatiemarkt 2020 Medisch Spectrum Twente, 2020, Enschede/The Netherlands, poster presentation “Stoppen met Roken? Kies de methode die bij u past!”

Facharbeitskreis Beratungsstellen | Der Paritätische Nordrhein-Westfalen, Bereich: Kinder und Familie – Fachgebiet Psychosoziale Beratung, 2019, presentation “Beratung 2.0 – Beratungsformen der Zukunft”

ERS European Respiratory Society International Congress, 2019, Madrid/Spain, poster discussion “Blended face-to-face and web-based smoking cessation treatment (BSCT): a description of patients’ user experience (UX)”

SRNT-E Society for Research on Nicotine and Tobacco Europe 19th Annual Conference, Oslo/Norway, 2019, poster presentation „Blended face-to-face and Web-based Smoking Cessation Treatment: a description of patients‘ user experience“

Digital Youth Work and Innovation, Warsaw/Poland, 2019, oral presentation & world café “Education and Training for Youth Work in the Age of Smartphones and Social Media”

Supporting Health by Tech IX, Groningen, 2019, oral presentation “How do we measure adherence to a Blended Smoking Cessation Treatment?”

Medisch Spectrum Twente Wetenschapsdag, 2019, Enschede/The Netherlands, oral presentation “Blended Face-to-face and Web-based Smoking Cessation Treatment: a description of patients’ user experience”

YOWOMO2.0-Train Conference, 2019, London/UK, oral presentation “”Education and Training for Youth Work in the Age of Smartphones and Social Media”

NNvT Nederlands Netwerk voor Tabaksonderzoek Congress, 2019, Utrecht/The Netherlands, oral presentation “Adherence to a blended smoking cessation treatment – How do we measure adherence, how do patients adhere and what predicts adherence?”

Jugendhilfe Goes Digital – Fit für die digitalisierte Kinder- und Jugendhilfe?, 2019, Ahaus/Germany, workshop “Digital or dead? – Mediatisierung und digitale Innovation in der Jugendhilfe – Strategieworkshop für Leitungskräfte”

Jugendhilfe Goes Digital – Fit für die digitalisierte Kinder- und Jugendhilfe?, 2019, Ahaus/Germany, oral presentation “YOWOMO – Fortbildungen für die Kinder- und Jugendhilfe im Zeitalter von Smartphones und Social Media”

eHealthmarkt Medisch Spectrum Twente, 2019, Enschede/The Netherlands, poster presentation “Stoppen met Roken? Kies de methode die bij u past!”

ERS European Respiratory Society International Congress, 2018, Paris/France, thematic poster “Adherence to a blended smoking cessation treatment”

Saxion Research Conference, 2018, Enschede/The Netherlands, poster presentation “Exploring levels and predictors of adherence to a blended smoking cessation treatment”

Arbeitskreis Offene Kinder- und Jugendarbeit Kreis Coesfeld, 2018, Coesfeld/Germany, workshop “Digitalisierung in der Jugendarbeit”

Supporting Health by Tech VIII, 2018, Enschede/The Netherlands, oral presentation “Adherence and predictors of adherence to a blended face-to-face and web-based smoking cessation treatment”

DIG-IT UP!, 2018, Ferrara/Italy, session “The survival of the (digitally) fittest – Digital Youth Work from the perspective of professional development”

14th Tomas More International Days “Social Work in Digital Times – The Digital Gap”, 2018, Geel/Belgium, workshop “How to deal with ethical challenges in digital youth work”

Medical Spectrum Twente Hospital, 2017, Enschede/The Netherlands, science evening oral presentation “Adherence to blended smoking cessation treatment”

Digital Youth Work, 2017, Vienna/Austria, poster presentation “Youth Work mobile 2.0 – Train – Education and training for youth work in the age of smartphones and social media”

LWL-Bildungszentrum Jugendhof Vlotho, 2017, Vlotho/Germany, symposium “Kinder und Jugendliche im Netz – Fachtag zur professionellen Arbeit mit Kindern und Jugendlichen im Zeitalter von Smartphones und Social Media”

Persuasive Technology XII, 2017Amsterdam/The Netherlands, doctoral consortium presentation “Exploring patients’ and counsellors’ user experiences of a blended smoking cessation treatment”

Aldegrever-Gymnasium, 2017, Soest/Germany, oral presentation “Jugendarbeit im Zeitalter von Social Media und Smartphones”

Supporting Health by Technology VII, 2016, Groningen/The Netherlands, oral presentation “The best of both worlds?” – Blending face-to-face and online counselling to improve smoking cessation treatment

Medical Spectrum Twente Hospital, 2015, Enschede/The Netherlands, science evening oral presentation “Blended Smoking CessationTreatment (RookvrijLeven-Studie)”

DIGITAL LITERACY: Policies, research and good practices, 2015, Padova/Italy, oral presentation “Youth Work Mobile 2.0 (YOWOMO2.0) – A competence framework for youth work in the age of smartphones and social media”

SNIC 2015 – Social Networking in Cyberspace

conference, 2015, Wolverhampton/UK, oral presentation “Youth Work Mobile 2.0 (YOWOMO2.0) – A competence framework for youth work in the age of smartphones and social media”

Health Valley, 2015, Nijmegen/The Netherlands, pecha kucha “Shaken or stirred? – The perfect mix of online and face-to-face smoking cessation treatment” (

IR15 – Association of Internet Researchers conference, 2014, Daegu/South Korea, doctoral colloquium discussion “The best of both worlds? – Bridging online and offline communication in health & care”

TGS TRAINING AND SUPERVISION

Date	Name	EC
28-09-2019	ERS International Congress	1,0
12-09-2019	SRNT Europe conference	1,0
29-05-2019	Digital Youth Work and Innovation	1,0
16-05-2019	Supporting Health by Technology IX	1,0
07-05-2019	Citizenship in a Digital Era	2,0
18-04-2019	WETENSCHAPSSYMPOSIUM MST	1,0
15-02-2019	Congres Nederlands Netwerk voor Tabaksonderzoek	1,0
21-01-2019	E-healthmarkt in MST	0,5
21-06-2018	Saxion Research Conference	1,0
01-06-2018	Supporting Health by Technology VIII	1,0
27-11-2017	Digital Youth Work	1,0
05-10-2017	Digitale Medien - analoge Wirklichkeiten	0,5
26-04-2017	Children and Youth on the Net	1,0
03-04-2017	Persuasive Technology XII	1,0
23-01-2017	Becoming a Digital Citizen: an Introduction to the Digital Society	0,5
27-05-2016	Supporting Health by Technology VII	1,0
23-05-2016	eHealth: Combining Psychology, Technology and Health	1,0
14-12-2015	Workshop Human-Technology Relations in Ethics, Design and Science: Mediation Theory and Philosophy of Technology	2,0
10-12-2015	Digital Literacy: Policies, research and good practices conference	1,0
17-11-2015	Trends in e-Psychology MOOC	1,0
13-09-2015	Technical writing & editing	2,0
03-09-2015	Social Networking in Cyberspace conference (SNIC)	1,0
18-05-2015	Technical writing and editing	2,0
23-04-2015	Ethics of Technology	1,0
18-03-2015	Health Valley Event	1,0
01-03-2015	Good Clinical Practice cursus	1,0
21-10-2014	IR15: Boundaries and Intersections Doctoral colloquium and 3-day conference of The Association of Internet Researchers	2,0
01-09-2014	Epidemiologie Medical Spectrum Twente	1,0
08-05-2014	Scientific Information: Searching, Managing and Publishing	1,0
01-05-2014	Training on the Job (Taster Days) at Pulmomary department/MST, Hands-On Training Rokendebaas at Tactus	1,0
01-04-2014	Informal learning preparing the METC application	2,0
13-03-2014	TGS introductory workshop 2-day course	0,5